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EuroGCT Deliverable D4.7: Information collation, report on collation of existing information and links on where to seek information and guidance- Version 2.0

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Deliverable Report

Grant Agreement Number: 965241

Project acronym: EuroGCT

***Project title: European Consortium for Communicating
Gene and Cell Therapy Information***

Deliverable: D.4.7. Information collation

***Report on collation of existing information and links on where to
seek information and guidance***

Date: 31st July 2023

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List of acronyms

ATMP: Advanced Therapy Medicinal Products

ELSI: Ethical, Legal and Societal Issues

EMA: European Medicines Agency

EU: European Union

EuroGCT: The European Consortium for Communicating Gene and Cell Therapy Information

ICH: The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

WP: Work Package

GA: Grant Agreement

0. Summary of D4.7 Resubmission

Deliverable D.4.7 "Information collation - Report on collation of existing information and links on where to seek information and guidance" describes the **methodology and tools** used for collecting and selecting information regarding gene and cell therapy development. It focuses on **how** the information is collated rather than summarising the collated information itself.

The published and subsequent output of the methodological reporting in this early-project deliverable is presented in **D4.2**. The collated information is presented in the EuroGCT website Research Pathways section (<https://www.eurogct.org/research-pathways>) as a searchable and filterable database. New content developed by the EuroGCT project and signposting to additional collated resources is now continually incorporated into this database, and this will continue throughout the duration of the project.

The overall objective of WP4 is to develop an information hub for the research and regulatory communities, facilitating their access to high-quality information on the practical steps needed for cell and gene-based therapy development at each stage of the product development process. This deliverable, on the means of information-gathering, constitutes the foundation of all information provision by WP4. It forms the basis of all deliverables within WP4, from past deliverables (**D4.4** Regulator Engagement Strategy, **D4.8** Initial Landscape Mapping, and **D4.9** Initial Information on Practical Steps) to deliverables due now (**D4.1** Landscape Mapping, and **D4.2** Resources on Practical Steps), and future deliverables (**D4.3** Searchable Map, **D4.5** Knowledge Sharing Function, and **D4.6** Hub for the Research and Regulatory Communities). *How* the information is collated feeds into what information is selected, information quality and whether it meets the needs of the stakeholders. It therefore affects every output from WP4. For this reason, it is of fundamental importance to report on the details of the approaches we have taken. The field of gene and cell therapy is rapidly advancing, and so is the relevant scientific and legal information. The EuroGCT WP4 has been and will continue to review and update our methodology for collecting this information throughout the project span. Updates within the current reporting period have been reflected in this report within relevant sections and annexes.

1. Objectives of the deliverable

The overall objective of WP4 is to develop an information hub for the research and regulatory communities to facilitate their access to high-quality information on the practical steps needed for cell and gene-based therapy development.

Deliverable **D.4.7** "Information collation" constitutes the root of WP4. This deliverable reports on the methodology for collecting and selecting (i.e. collation) of information regarding the ATMP product development pathway and therefore contributes to the content of the EuroGCT website (WP4 Tasks 1 to 3 in GA); the mapping of actors and networks active in the field of gene and cell therapy (WP4 Task 4 in GA); and the identification of existing procedures, times, or spaces for engagement with regulators (WP4 Task 5). To meet these WP4 objectives, relevant and reliable information must be identified and made accessible on the EuroGCT website.

The information needed to achieve these objectives is extensive, various and scattered. The methodology on the collection and selection needs to be clear and detailed. Hence,

Deliverable **D.4.7** “Information collation” presents *how* such information is being collected by describing the methodological approach and the tools we used. The information and links collated at the time of submission of this deliverable are provided as appendices to **D4.7**. We note that the highly specialist nature of the information collated in WP4 means that the methodology for identification and selection of information and links relevant to this WP requires a specific approach separate from the approach described in **D1.1** and **D1.3**, which describe collation of information suitable for dissemination to public audiences.

2. Methodological approach

Several complementary approaches have been used to collect existing information on cell and gene therapy to meet WP4 objectives:

a) Scientific and legal research on existing gene and cell therapy general information

We started by conducting a scientific and legal watch through searching for gene and cell therapy information on institutional websites (including the European Commission, national agencies and the European Medicines Agency), and scientific/societal sources (such as learned societies, patient organisations, research infrastructures, clinical trials databases, and more organisations active in the field). Please see **D4.7 Annexe 1** for the detailed list of such websites.

We note that information and guidance for patients seeking for clinical trials and available products is partially addressed in **D3.2 Decision-making Resources** and **D3.9 Initial fact sheets and resources** (examples of resources include ‘Do you have a decision to make around your own healthcare, or the healthcare of a loved one?’, ‘What conditions can currently be treated using gene and cell therapy?’, ‘What is the clinical trials process?’, and ‘What are unproven therapies?’). It is beyond the scope of our project to be a ‘gatekeeper’ which endorses specific treatments and clinics, and indeed it could compromise the project’s credibility were we to do so (this issue has been discussed by the International Society for Stem Cell Research, which also reached this conclusion). However, the resources presented both in **WP4** (Research Pathways information hub) and **WP3** (especially a subset reported in **Ds 3.2** and **3.9**) will help facilitate informed conversations between patients and healthcare professionals, as well as directing them to relevant information.

b) Legal watch for European Union legislation on gene and cell therapy

We then set up a specific legal watch complementary to the above general scientific and legal watch to search for all binding EU texts that apply to ATMP. Because EU texts are centralised in the Eur-Lex website, we mainly focused our research here and then combined with those on the EU institutions’ websites. For the full list of applicable EU binding texts, please see **Annexe 2.a**. The the links collated in this Annexe have been published on the website within each published EuroGCT full entries inside ‘Key Research Pathways’ (<https://www.eurogct.org/research-pathways/key-research-pathways>). See all ‘European Union Legislation’ sections within. An example can be directly accessed here: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/standard-marketing-authorisation-pathway#para-414>. More examples can be found within the ‘Public Involvement and Data’ section and the sub-entries within ‘Commercialisation / Market Access for ATMPs’. A list of published full entries can be found in **D4.1 Annexe 1**.

c) Research on information available on applicable guidelines

In addition to the binding legal framework, ATMP development is subject to many guidelines and guidance that need to be identified and collated. We have researched the information available on applicable guidelines, especially on the EMA website, the European Commission website and ICH. For the full list of applicable European guidelines, please see **D4.7 Annexe 2.b**. The the links collated in this Annexe have been published on the website within each published EuroGCT resources in 'Key Research Pathways', and all 'European Union Guidance' sections within. An example can be accessed at:

<https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/standard-marketing-authorisation-pathway#para-415>. A list of published full entries can be found in **D4.1 Annexe 1**.

d) Participation in conferences and workshops to collect information

Attending selected scientific conferences and workshops allows us to collect up-to-date information, and to identify the main issues in the field. We have created an evolutive list of events to attend. For the full list of attended conferences, workshops and seminars, please see **D4.7 Annexe 2.c**.

e) Collecting information from EuroGCT partners

Two approaches have been used to collect relevant information from EuroGCT partners. First, partners can send us relevant information via emails. Second, we have created ELSI Working Groups in accordance with the Research Pathways draft tree (See **D4.8**). Partners can choose to join and contribute to one or more ELSI Working Groups base on their expertise and interest.

f) Creation of ELSI Bibliography on gene and cell therapy

Literature regarding ELSI of gene and cell therapy, especially ATMP, tends to be scattered and not easily accessible. We have established a specific methodology to address this--we listed the main Social and Human Sciences databases and to search within by key words "ATMP" or "gene and cell therapy" and "European Union". This work is divided in two phases: phase one covers what we consider to be the most used Social and Human Sciences databases, especially in law; phase two covers complementary Social and Human Sciences databases (**D4.7 Annexe 2.d**). A template of research record for bibliography has been established (**D4.7 Annexe 3.a**). The the links collated in these Annexes have been published on the website within each published EuroGCT resources in 'Key Research Pathways', and all 'Relevant literature' section within. An example can be accessed here: <https://www.eurogct.org/research-pathways/commercialisation/market-access-atmps/standard-marketing-authorisation-pathway#para-1393>. A list of published full entries can be found in **D4.1 Annexe 1**.

g) Creation of templates

For dissemination of the information and resources collated for the Research and Regulatory communities (WP4), EuroGCT will provide direct links to relevant scientific articles, ELSI and legal literature whenever possible. To enhance accessibility, EuroGCT also aims to provide lay summaries, accessible to various non-specialist stakeholders. This will be done by contacting the authors or the development of lay summaries written by the ELSI Network of

Expertise. A EuroGCT template for lay summaries of social and human sciences literature (**D4.7 Annexe 3.b.**) and guidelines for lay summaries (**D4.7 Annexe 3.c.**) have been established. The two EuroGCT templates were reviewed by members of the ELSI Network of Expertise and by Partners 1 and 2. Finally, a follow-up table (**D4.7 Annexe 3.d.**) has been created to keep track of requests for lay summaries and translation.

h) ELSI Network of Expertise

The ELSI network of expertise is constituted of EuroGCT partners and experts external to EuroGCT who have knowledge, expertise and research interest on the ELSI aspects of gene and cell therapy. These external members have been recruited through EuroGCT partners' own networks, especially those of partner 2. They are also being identified through the ELSI bibliography being developed as social and human sciences authors who have published on the ELSI aspects of gene and cell therapy in recognised social and human sciences reviews. See **D4.7 Annexe 4** for the list of social and human sciences research centres that have been identified.

3. Summary of activities and outputs

Section 3 summarises our results to date regarding identification and collection of information using the methodological approaches described in **2** above, and also outlines our ongoing work.

a) Selection of a common terminology for use throughout EuroGCT

In addition to the general objectives of information collation (see **1**), the scientific & legal watch described in **2** above has contributed substantially to ongoing work focussed on defining a common vocabulary for EuroGCT. Use of a precise, defined vocabulary is necessary considering the multi-disciplinary nature of the consortium including the core ELSI team, as precise terminology helps both specialist and non-specialist audiences (including the general public) understand and navigate information provide both through the project and outside. WP4 work in this area has led to the choice of project key terms such as “development pathway”, “regulation”, “ATMP”, “medicines” but not “drugs” as general terms. The relevant key words and the works on definitions are also being integrated in the general overviews of each sub-entry in the Research Pathways section (see **D4.8**). For instance, the general overviews include a “Definitions” section, which highlight and clarify which words are used by which type of stakeholders considering this stage of the development pathway.

The list of the websites that have been consulted so far during the scientific & legal watch and research for general information are listed in full in **D4.7 Annexe 1**.

b) Collation of information on European Union legislation on gene and cell therapy

The legal watch and research for the applicable European Union legislation on gene and cell therapy described in **2** above has led to the development of a 'binding texts' list (see **D4.7 Annexe 2.a** for a full list). In this list specific binding texts regarding ATMP development have been compiled. The list includes binding texts regarding medicinal products, medical devices, human cell and tissues, and ATMP specifically. In addition to binding texts, the legal watch has contributed to the identification and compilation of all the applicable guidance regarding ATMP development. (See **D4.7 Annexe 2.b** for a full list).

c) Collation of regulatory and ELSI information on gene and cell therapy

Due to the increasingly fast development of ATMPs and their regulation, it has been useful to get up-to-date information directly by attending relevant conferences, workshops, and seminars, and by creating thematic bibliographies listing all social and human sciences articles from relevant databases (see **D4.7 Annexe 2c** for full list of attended conferences, workshops, and seminars). These conferences, workshops, and seminars have given us thorough insights on the latest scientific developments in the field of gene and cell therapy (for instance, in the field of human genome editing), including on the latest regulatory developments (for instance, recent adoption of the French law on bioethics, adoption by the EMA on flowcharts on quality, non-clinical and clinical developments of ATMP).

The collection of information from EuroGCT partners has started. EuroGCT ELSI working groups are set up and each have agreed roadmaps for information collation. The ELSI Working groups are currently working on providing general overviews and full contents for each sub-entry of the Research Pathway Tree (see **Ds 4.1** and **4.8**).

The ELSI Bibliography on gene and cell therapy is compiled for each sub-entry of the Research Pathways section, and will be expanded as new sub-entries are developed.

d) Role of ELSI NoE

The ELSI Network of Expertise is operational while still being expanded. It has contributed to the review of templates. It is also involved in the reviews of the first factsheets being developed in WP3. It has also been involved in providing first drafts for the content of some sub-entries of the Research Pathways section, where the expertise was not available within the EuroGCT consortium (e.g. sub-entries on data protection). It will also be involved in providing lay summaries of social and human sciences literature and lay summaries of guidelines.

Finally, we note that all the methodological approaches of information collation have contributed to the development of general overview sub-entries in the Research Pathways section of the website, providing initial landscape mapping (see **D4.8**) and initial information on practical steps (see **D4.9**) as well as to the development of a EuroGCT strategy for stakeholder engagement with regulators (see **D.4.4**). They are now being used to complete the landscape mapping work for all sub-entries the Research Pathways section (see **D4.1**).

4. Conclusions and future steps

The methodological approach on information collation we have described constitutes the foundation of all information provision by WP4. The activities described in this deliverable are long-term and will continue to be reviewed and updated throughout the project's duration.

All of the aforementioned channels for information collation are active and have provided results. The information collected so far using the methodology described has been published in the Research Pathways section on the EuroGCT website, <https://www.eurogct.org/research-pathways> (see **D4.2**) and is also detailed in the Annexes to this deliverable. These annexes provide more details on the concrete methodological approaches have developed and implemented on collation of information relevant to researchers and regulators active in cell and gene therapy, and will be updated as the project progresses.

5. List of Annexes

Annexe 1. Scientific & Legal watch: consulted websites (updated July 2023)

Annexe 2. Legal watch and research for information results

- 2.a. List of binding texts applicable to ATMP development (updated July 2023)
- 2.b. List of guidelines applicable to Advanced Therapy Medicinal Products (updated July 2023)
- 2.c. List of attended conferences, workshops and seminars (updated July 2023)
- 2.d. List of Social and Human Sciences databases

Annexe 3. Templates

- 3.a. Template of research record for bibliography
- 3.b. Template of lay summaries of Social and Human Sciences literature
- 3.c. Template of lay summaries of Guidelines
- 3.d. Follow-up table for requests of lay summaries and translations

Annexe 4. List of Social and Human Sciences research centres active on gene and cell therapy (updated July 2023)

EuroGCT

Annex 1 to Deliverable D.4.7

Scientific & Legal watch: List of visited websites and links

Last Update: 11/07/2023

This section contains a list of websites the EuroGCT project team has visited to seek information and guidance regarding gene and cell therapy development. The collated list of websites comprises our sources of information, and we are using this list and the resources within to collectively provide the research and regulatory communities information on:

1. resources: information and links on where to seek further information and guidance
2. actors: the gene and cell therapy stakeholders in Europe

Since the last reporting period (month 12), we've updated this collated list with additional actors we've identified, with a focus on actors and their activities beyond France and the UK.

More details on the inventory of resources and actors can be found on the EuroGCT website (<https://www.eurogct.org/>). The revamped Research Pathways section (see <https://www.eurogct.org/research-pathways>, and D4.2 Resources on practical steps) provides an interactive, searchable and filterable inventory of resources on cell and gene therapy development. The Actors and Network page (<https://www.eurogct.org/research-pathways/actors-and-networks>) maps the actors in Europe and will form the basis for Deliverable D4.3 Searchable map that is due at month 48.

This compiled list is indicative and will continuously be expanded throughout the project's duration. The contents on the EuroGCT website and the Research Pathways section within will also continue to be iteratively updated.

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II. Institutional sources

A. Europe

1. European Union

- European Medicines Agency (EMA):
 - The latest news
 - « Open consultations » and « Events » (Potential events to be reported on our conference doc and on ELSIBI) in « News & Events »
 - CAT Monthly reports (<https://www.ema.europa.eu/en/committees/cat/cat-agendas-minutes-reports#minutes-section>)
 - Guidance documents
 - Tools and resources
- European Commission (EC) :
 - On Public health policy : « blood, tissues, and organs », « health technology assessment », « medicinal products for human use », « medical devices », « research and innovation in health »
 - Research and Innovation
 - Single market
- European Group on Ethics in Science and New Technologies (EGE)
- Court of Justice of the EU
- Expert Panel on effective ways of investing in health

- [EUnetHTA](#)
- European Data Protection Board (EDPB)
https://edpb.europa.eu/edpb_en
- [European Network of Research Ethics Committees \(EUREC\)](#)

2. Council of Europe

- [European Directorate for the Quality of Medicines and Healthcare \(EDQM\)](#)
- [Committee on Bioethics \(DH-BIO\)](#)
- [European Committee on Organ Transplantation \(CD-P-TO\)](#)
- [European Committee on Blood Transfusion \(CD-P-TS\)](#)

3. Other

- [European Patent Office \(EPO\)](#)

4. National Medicines Agencies

- Austria [Austrian Agency for Health and Food Safety](#)
- Belgium [Federal Agency for Medicines and Health Products \(FAMHP\)](#)
- Bulgaria [Bulgarian Drug Agency](#)
- Croatia [Agency for medicinal products and medical devices of Croatia](#)
- Cyprus [Ministry of Health - Pharmaceutical Services](#)
- Czechia [State Institute for Drug Control](#)
- Denmark [Danish Medicines Agency](#)
- Estonia [State Agency of Medicines](#)
- Finland [Finnish Medicines Agency](#)
- France [National Agency for the Safety of Medicine and Health Products](#)
- Germany [Federal Institute for Drugs and Medical Devices](#)
- Germany [Paul Ehrlich Institute](#)
- Greece [National Organization for Medicines](#)
- Hungary [National Institute of Pharmacy and Nutrition](#)
- Iceland [Icelandic Medicines Agency](#)
- Ireland [Health Products Regulatory Authority \(HPRA\)](#)
- Italy [Italian Medicines Agency \(AIFA\)](#)
- Latvia [State Agency of Medicines](#)
- Liechtenstein [Office of Health / Department of Pharmaceuticals](#)
- Lithuania [State Medicines Control Agency](#)
- Luxembourg [Ministry of Health](#)
- Malta [Malta Medicines Authority \(MMA\)](#)
- Netherlands [Medicines Evaluation Board](#)

- Netherlands Healthcare and Youth Care Inspectorate, Ministry of Health, Welfare and Sport
- Norway Norwegian Medicines Agency (NoMA)
- Poland Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Poland Chief Pharmaceutical Inspectorate
- Portugal National Authority of Medicines and Health Products (INFARMED)
- Romania National Authority of Medicines and Medical Devices of Romania
- Slovakia State Institute for Drug Control
- Slovenia Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
- Spain Spanish Agency for Medicines and Health Products
- Sweden Swedish Medical Products Agency

5. National Health Technology Assessment (HTA) Bodies

- Austria Austrian Institute for Health Technology Assessment (AIHTA)
- Belgium Belgian Health Care Knowledge Centre (KCE)
- England The National Institute for Health and Care Excellence (NICE)
- France Haute Autorité de Santé (HAS)
- Hungary National Institute of Pharmacy and Nutrition (OGYÉI)
- Germany Gemeinsamer Bundesausschuss (GBA)
- Germany The independent Institute for Quality and Efficiency in Health Care (IQWiG)
- Ireland The National Centre for Pharmacoeconomics (NCPE)
- Italy Italian Medicines Agency (AIFA)
- Netherlands The National Health Care Institute (ZIN)
- Norway Norwegian Medicines Agency (NoMA)
- Portugal National Authority of Medicines and Health Products (INFARMED)
- Scotland Scottish Medicines Consortium (SMC)
- Spain Spanish Agency for Medicines and Health Products (AEMPS)
- Sweden Tandvårds- och läkemedelsförmånsverket (TLV)

B. International

- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
- International Bioethics Committee (IBC) of the UNESCO

- Council for International Organizations of Medical Sciences (CIOMS) <https://cioms.ch/>
- [World Health Organization \(WHO\)](#)
- Organisation for Economic Co-operation and Development (OECD) <https://www.oecd.org/>

C. France

- [Comité Consultatif National d'Éthique \(CCNE\)](#)
- [ANSM](#) (Agence National de Sécurité du Médicament et des produits de santé)
- [Agence de la biomédecine](#)
- [Haute Autorité de Santé \(HAS\)](#)
- [Office parlementaire d'évaluation des choix scientifiques et technologiques \(OPECST\)](#)

D. UK

- [Human Tissue Authority \(HTA\)](#)
- [Medicines & Healthcare products Regulatory Agency \(MHRA\)](#)
- [NHS Blood and Transplant \(NHSBT\)](#)
- [UK Research and Innovation \(UKRI\)](#)
- [Department of Health and Social Care](#)
- [Nuffield Council on Bioethics](#)
- [Cell and Gene Therapy Catapult](#)
- [HFEA](#)
- National Institute for Health and Care Excellence (NICE)
<https://www.nice.org.uk/>
- Accelerated Access Collaborative (AAC)
<https://www.nice.org.uk/aac>
- Parliamentary Office of Science & Technology (POST)
- House of Lords Science & Technology Committee
- National Institute for Biological Standards and Control (NIBSC):
<http://www.nibsc.org/> (which hosts the UK stem cell bank)
- The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)
- National Institute for Health Research (NIHR)
<https://www.nihr.ac.uk/>
- Innovate UK <https://www.ukri.org/councils/innovate-uk/>
- UKRI Innovate UK KTN <https://iuk.ktn-uk.org/>
- National Health Service (NHS) <https://www.nhs.uk/>
- UK Information Commissioner's Office (ICO) <https://ico.org.uk/>

E. USA

- National Center for Advancing Translational Sciences (NCATS)
<https://toolkit.ncats.nih.gov/>
- National Institute of Standards and Technology (NIST)
<https://www.nist.gov/>
- National Institutes of Health (NIH) <https://www.nih.gov/>

III. Scientific/societal sources

A. Learned Societies

- o [Société Française de Thérapie Génique et Cellulaire](#)
- o [European Society of Gene and Cell Therapy](#)
- o International Society for Cellular Therapy (ISCT):
<http://www.celltherapysociety.org/>
- o International Society for Stem Cell Research (ISSCR): <http://www.isscr.org/>
- o American Society of Gene and Cell Therapy <https://asgct.org/>
- o The British Society for Immunology <https://www.immunology.org/>
- o [European Society of Human Genetics \(ESHG\)](#)
- o [American Society of Gene & Cell Therapy \(ASGCT\)](#)
- o [Australasian Gene and Cell Therapy Society \(AGCTS\)](#)
- o [German Gene Therapy Society \(DGGT\)](#)
- o [Netherlands Society of Gene and Cell Therapy \(NVGCT\)](#)
- o [Swedish Society of Gene and Cell Therapy \(SSGCT\)](#)
- o [Society for Inherited Metabolic Disorders \(SIMD\)](#)

B. Patient Associations

- o [Orphanet](#) surtout « Actualités politiques » dans la Newsletter Orphanews
- o The Patients Network for Medical Research and Health (EGAN):
<http://www.egan.eu/>
- o European Organisation for Rare Diseases (Eurordis):
<http://www.eurordis.org/fr>
- o Genetic Alliance UK <https://geneticalliance.org.uk/>
- o Patient Engagement Management Suite <https://pemsuite.org/>
- o European Patients' Forum www.eu-patient.eu
- o European Patients' Academy on Therapeutic Innovation (EUPATI)
<https://eupati.eu/>
- o Lung Cancer Europe (LuCE) <https://www.lungcancereurope.eu/>
- o Parkinson's UK <https://www.parkinsons.org.uk/>

C. Business Associations

- Leem Les entreprises du médicament
- Map MedTech (News)
- Map BioPharma (News)
- UK Bioindustry Association (BIA): <http://www.bioindustry.org/home/>
- EuropaBio
- Alliance for Regenerative Medicine <https://alliancerm.org/>
- The Association of the British Pharmaceutical Industry (ABPI) <https://www.abpi.org.uk/>
- BioPhorum C> <https://www.biophorum.com/phorum/cell-and-gene-therapy/>
- ATMP manufacture group <https://atmpmanufacture.org>
- European Federation of Pharmaceutical Industries and Associations (EFPIA) <https://www.efpia.eu/>
- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) <https://www.eucope.org/>

D. National and regional networks

- ATMP Sweden <https://atmpsweden.se/>
- Stem Cells Australia <https://stemcellsaustralia.edu.au/>
- The Advanced Therapy Treatment Centres (ATTC) Network <https://www.theattcnetwork.co.uk/>
- Academic Health Science Networks (AHSNs) <https://www.ahsnnetwork.com/>
- NHLBI Gene Therapy Resource Program <https://www.gtrp.org/>
- NIST Genome Editing Consortium <https://www.nist.gov/programs-projects/nist-genome-editing-consortium>
- ATMP Manufacturing Ireland
- Advanced Therapy Network (ATN)
- Deutsche Gesellschaft für Gentherapie e.V. (DG-GT)
- German Stem Cell Network for Basic & Applied Stem Cell Research <https://gscn.org/>
- European Society for Blood and Marrow Transplantation (EBMT)
- EuroStemCell
- University College London (UCL) Future Targeted Healthcare Manufacturing Hub <https://www.ucl.ac.uk/biochemical-engineering/research/research-and-training-centres/future-targeted-healthcare-manufacturing-hub>
- Innovative Genomics Institute (IGI) at UC Berkeley and UCSF

E. International consortium and networks

- Global Alliance for Genomics and Health (GA4GH) <https://www.ga4gh.org/>
- International Consortium for Personalised Medicine - ICPeMed

- [International Rare Diseases Research Consortium \(IRDiRC\)](#)
- [The International Alliance for Biological Standardization \(IABS\)](#)
- [Forum for Innovative Regenerative Medicine \(FIRM\)](#)
-

F. Translational research centres, organisations

- EATRIS <https://eatris.eu/>
- The Global Alliance for iPSC Therapies (GAI^T) <http://www.gait.global/>
- Cell and Gene Therapy Catapult <https://ct.catapult.org.uk/>
- ECRIN <https://ecrin.org/>
- CCRM <https://www.ccrm.ca/>

G. Related projects

- European Joint Programme on Rare Diseases (EJP RD) <https://www.ejprarediseases.org/>
- RESTORE <https://www.restore-horizon.eu/opportunity/>
- ADVANCE <https://eatris.eu/projects/advance/>
- Transmed Academy <https://eatris.eu/transmed-academy/>
- T2Evolve <https://t2evolve.com/>
- [COST Action HAPLO-iPS](#)
- [AUTOSTEM](#)
- [AIDPATH](#)
- [COST Action CorEuStem](#) – The European Network for Stem Cell Core Facilities
- [GAPP JOINT ACTION](#) – Co-Funded by the Health Programme of the EU
- [I-BioLex](#) – Fragmentation and defragmentation of the law on biomedical innovations
- [SIENNA Project](#)
- Strengthening Training of Academia in Regulatory Science (CSA STARS) <https://www.csa-stars.eu/index.html>
- PaVe-GT: Paving the Way for Rare Disease Gene Therapies <https://pave-gt.ncats.nih.gov/>

H. Charities

- Association of Medical Research Charities (AMRC) <https://www.amrc.org.uk/>
- Health data research UK (HDR UK) <https://www.hdruk.ac.uk>
- Shared Learning Group on Involvement <https://slginvolvement.org.uk/>

- Health Research Charities Ireland (HRCI) <https://hrci.ie/>

I. Biobanks, registries, databases

- European Bank For Induced Pluripotent Stem Cells (EBiSC)
- Human pluripotent stem cell registry (hPSCreg) <https://hpscereg.eu/>
- EuroBioBank <http://www.eurobiobank.org/>
- UK Biobank <https://www.ukbiobank.ac.uk/>
- The National Gene Vector Biorepository (NVGB)
<https://www.ngvbcc.org/Home.action>
- European Union Drug Regulating Authorities Clinical Trials Database (EudraCT) <https://eudract.ema.europa.eu/>
- VigiBase <https://www.who-umc.org/vigibase/vigibase/>
- EudraVigilance <https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance> and
<https://www.adrreports.eu/en/index.html>
- HealthData <https://healthdata.gov/>
- The European Genome-phenome Archive (EGA) <https://ega-archive.org/>
- RD-Connect online Genome-Phenome Analysis Platform <https://platform.rd-connect.eu/>
- DECIPHER (phenotypic and genotypic data)
<https://www.deciphergenomics.org/>
- BBMRI-ERIC ELSI Knowledge Base: information on ELSI-related matters relevant to biobanking <https://bbmri-eric.eu/elsi-knowledge-base/>
- EU Clinical Trials Register <https://www.clinicaltrialsregister.eu/>
- Netherlands Trial Register <https://www.trialregister.nl/>
- Australian New Zealand Clinical Trials Registry
<https://www.anzctr.org.au/default.aspx>
- International Standard Randomised Controlled Trial Number Register (ISRCTN Register) <https://www.isrctn.com/>
- NIH Clinical Trials Database <https://clinicaltrials.gov/>
- The Journal of Gene Medicine clinical trial site
<https://a873679.fmphost.com/fmi/webd/GTCT>
- Clinical trials sponsored by NCI <https://www.cancer.gov/about-cancer/treatment/clinical-trials>
- WHO Human Genome Editing (HGE) Registry [Human Genome Editing Registry \(who.int\)](https://www.who.int/human-genome-editing)

J. Publisher/Journals

- Cell and Gene Therapy Insights <http://www.insights.bio/cell-and-gene-therapy-insights/home>
- Cell (and family of journal) <https://www.cell.com/>

- Springer Nature (and families of journals) <https://www.nature.com/> and <https://www.biomedcentral.com/>
- Science (and family of journals) <https://www.science.org/>
- Frontiers (and family of journals) <https://www.frontiersin.org/>
- Cytotherapy <https://www.isct-cytotherapy.org/>
- EMBO Journal <https://www.embopress.org/journal/14602075>
- StemBook <https://www.stembook.org/>
- Human Gene Therapy <https://www.liebertpub.com/loi/hum>
- Etc....

K. Other

- [RIS.WORLD & IFEP](#) by White-Tillet
- Regener8: <http://www.regener8.ac.uk/>
- RegMedNet: <https://www.regmednet.com/>
- [Généthique](#)
- [Forum européen de la bioéthique](#)
- [Institut européen de bioéthique \(IEB\)](#)
- Gene Therapy Net <https://www.genetherapynet.com/>

EuroGCT

Annex 2.a to Deliverable D.4.7

List of EU binding texts applicable to ATMP development

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I. Biological elements

1) Human blood

Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards **quality system standards and specifications for blood establishments** (Text with EEA relevance) C/2016/4641, OJ L 199, 26.7.2016, p. 14–15

- [Original text](#)

Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards **temporary deferral criteria for donors of allogeneic blood donations** (Text with EEA relevance), OJ L 366, 20.12.2014, p. 81–82

- [Original text](#)

Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to **maximum pH values for platelets concentrates at the end of the shelf-life** Text with EEA relevance, OJ L 97, 12.4.2011, p. 28–29.

- [Original text](#)

Directive 2005/62/EC of 30 September 2005 **implementing Directive 2002/98/EC** of the European Parliament and of the Council **as regards Community standards and specifications relating to a quality system for blood establishments** (Text with EEA relevance), OJ L 256, 1.10.2005, p. 41–48, CELEX number: 32005L0062

- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

Commission Directive 2005/61/EC of 30 September 2005 **implementing Directive 2002/98/EC** of the European Parliament and of the Council **as regards traceability requirements and notification of serious adverse reactions and events** (Text with EEA relevance), OJ L 256, 1.10.2005, p. 32–40, CELEX number: 32005L0061

- [Original text](#)

Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council **as regards certain technical requirements for blood and blood components** (Text with EEA relevance), OJ L 91, 30.3.2004, p. 25–39, CELEX number: 32004L0033

- [Original text](#)
- [Consolidated text](#)

Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 **setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components** and amending Directive 2001/83/EC; OJ L 33, 8.2.2003, p. 30–40, CELEX number: 32002L0098

- [Proposal \(Proposal for a Directive](#) of the European Parliament and of the Council **setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components** and amending Council Directive 89/381/EEC (COM (2000) 816 final - 2000/0323 (COD)) (Text with EEA relevance); (Submitted by the Commission on 26 January 2001), OJ C 154E, 29.5.2001, p. 141–163, CELEX number: 52000PC0816)
- [Original text](#)
- [Document summary](#)

2) Human tissues and cells

Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC **as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells** (Text with EEA relevance), OJ L 93, 9.4.2015, p. 56–68, CELEX number: 32015L0566

- [Original text](#)

Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC **as regards certain technical requirements for the coding of human tissues and cells** (Text with EEA relevance), OJ L 93, 9.4.2015, p. 43–55, CELEX number: 32015L0565

- [Original text](#)

Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain **technical requirements for the testing of human tissues and cells** Text with EEA relevance, OJ L 327, 27.11.2012, p. 24–25, CELEX number: 32012L0039

- [Original text](#)

2010/453/EU: Commission Decision of 3 August 2010 establishing **guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells** provided for in Directive 2004/23/EC of the European Parliament and of the Council (notified under document C(2010) 5278) Text with EEA relevance, OJ L 213, 13.8.2010, p. 48–50, CELEX number: 32010D0453

- [Original text](#)

Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council **as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells** (Text with EEA relevance), OJ L 294, 25.10.2006, p. 32–50, CELEX number: 32006L0086

- [Original text](#)
- [Consolidated text](#)

Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council **as regards certain technical requirements for the donation, procurement and testing of human tissues and cells** (Text with EEA relevance), OJ L 38, 9.2.2006, p. 40–52, CELEX number: 32006L0017

- [Original text](#)
- [Consolidated text](#)

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 **on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells**, OJ L 102, 7.4.2004, p. 48–58, CELEX number: 32004L0023

- [Proposal](#) (**Proposal for a Directive** of the European Parliament and of the Council **on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells** (COM (2002) 319 final - 2002/0128 (COD)), OJ C 227E, 24.9.2002, p. 505–521, CELEX number: 52002PC0319)
- [Amended proposal](#) (**Amended Proposal for a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells** (presented by the Commission pursuant to Article 250 (2) of the EC Treaty), COM/2003/0340 final - COD 2002/0128, CELEX number: 52003PC0340)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

3) Substances of human origin

(**Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC)

- [Proposal](#)

II. Genetically Modified Organisms (GMOs)

1) Clinical trials of medicinal products with GMOs for COVID-19

Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 **on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19)**, OJ L 231, 17.7.2020, p. 12–16, CELEX number: 32020R1043

- [Proposal](#) (**Proposal for a Regulation** of the European Parliament and of the Council **on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease**, COM/2020/261 final, CELEX number: 52020PC0261)
- [Original text](#)

2) Contained use of Genetically Modified Micro-Organisms

Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 **on the contained use of genetically modified micro-organisms** (Recast) (Text with EEA relevance), OJ L 125, 21.5.2009, p. 75–97, CELEX number: 32009L0041

- [Proposal](#) (**Proposal for a Directive** of the European Parliament and of the Council **on the contained use of genetically modified micro-organisms** (Recast), COM/2007/0736 final - COD 2007/0259, CELEX number: 52007PC0736)
- [Original text](#)
- [Document summary](#)

2000/608/EC: Commission Decision of 27 September 2000 concerning the **guidance notes for risk assessment** outlined in Annex III of Directive 90/219/EEC on the **contained use of genetically modified micro-organisms** (notified under document number C(2000) 2736) (Text with EEA relevance), OJ L 258, 12.10.2000, p. 43–48, CELEX number: 32000D0608

- [Original text](#)

3) Transboundary movements of GMOs

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 **on transboundary movements of genetically modified organisms** (Text with EEA relevance), OJ L 287, 5.11.2003, p. 1–10, CELEX number: 32003R1946

- [Proposal \(Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms, COM/2002/0085 final - COD 2002/0046, OJ C 151 E, 25.6.2002, p. 121–128, CELEX number: 52002PC0085\)](#)
- [Original text](#)
- [Document summary](#)

4) GMO Directive 2001-18 and amendments

Commission Implementing Decision (EU) 2021/1161 of 13 July 2021 amending Decision 2011/891/EU and Implementing Decisions (EU) 2017/1211, (EU) 2017/1212, (EU) 2017/2449, (EU) 2019/2085 and (EU) 2019/2086 as regards the **authorisation holder and its representative in the Union for the placing on the market of products containing, consisting of, or produced from certain genetically modified organisms** (notified under document C(2021) 5148) (Text with EEA relevance) (Only the Dutch text is authentic), C/2021/5148, OJ L 252, 15.7.2021, p. 1–6, CELEX number: 32021D1161

- [Original text](#)

Commission Implementing Decision (EU) 2021/184 of 12 February 2021 amending Decisions 2009/813/EC, 2009/814/EC and 2010/429/EU and Implementing Decisions 2012/82/EU, 2012/83/EU, 2012/347/EU, 2013/649/EU, (EU) 2015/683, (EU) 2015/684, (EU) 2015/685, (EU) 2015/686, (EU) 2015/687, (EU) 2015/688, (EU) 2015/689, (EU) 2015/693, (EU) 2015/695, (EU) 2015/696, (EU) 2015/700, (EU) 2015/701, (EU) 2015/2279, (EU) 2015/2281, (EU) 2016/1216, (EU) 2016/1217, (EU) 2017/1207, (EU) 2018/1111, (EU) 2018/2045, (EU) 2018/2046, (EU) 2019/1307, (EU) 2019/1308, (EU) 2019/1309, (EU) 2019/2083 and (EU) 2020/1360 as regards the **authorisation holder and its representative in the Union for the placing on the market of products containing, consisting of or produced from certain genetically modified organisms** (notified under document C(2021) 826) (Only the Dutch text is authentic) (Text with EEA relevance), C/2021/826, OJ L 55, 16.2.2021, p. 4–23, CELEX number: 32021D0184

- [Original text](#)

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 **on the transparency and sustainability of the EU risk assessment in the food chain** and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance.), OJ L 231, 6.9.2019, p. 1–28, CELEX number: 32019R1381

- [Proposal \(Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain](#) amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed

additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM/2018/0179 final - 2018/088 (COD), CELEX number: 52018PC0179)

- [Original text](#)
- [Document summary](#)

Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council **as regards the environmental risk assessment of genetically modified organisms**, OJ L 67, 9.3.2018, p. 30–45, CELEX number: 32018L0350

- [Original text](#)

Commission Implementing Regulation (EU) No 120/2014 of 7 February 2014 amending Regulation (EC) No 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and the Council as regards the Community reference laboratory for genetically modified organisms Text with EEA relevance, OJ L 39, 8.2.2014, p. 46–52, CELEX number: 32014R0120

- [Original text](#)

2009/770/EC: Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (notified under document C(2009) 7680) (Text with EEA relevance), OJ L 275, 21.10.2009, p. 9–27, CELEX number: 32009D0770

- [Original text](#)

Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC **on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission**, OJ L 81, 20.3.2008, p. 45–47, CELEX number: 32008L0027

- [Proposal \(Proposal for a Directive of the European Parliament and of the Council Amending Directive 2001/18/CE concerning the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred to the Commission, COM/2006/0920 final - COD 2006/0296, CELEX number: 52006PC0920\)](#)
- [Original text](#)

Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance), OJ L 368, 23.12.2006, p. 99–109, CELEX number: 32006R1981

- [Original text](#)
- [Consolidated text](#)

Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms, OJ L 10, 16.1.2004, p. 5–10, CELEX number: 32004R0065

- [Original text](#)
- [Document summary](#)

2002/813/EC: Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market, OJ L 280, 18.10.2002, p. 62–83, CELEX number: 32002D0813

- [Original text](#)
- [Consolidated text](#)

2002/812/EC: Council Decision of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products, OJ L 280, 18.10.2002, p. 37–61, CELEX number: 32002D0812

- [Original text](#)

2002/811/EC: Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 280, 18.10.2002, p. 27–36, CELEX number: 32002D0811

- [Proposal](#) (Proposal for a Council Decision establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC /* COM/2002/0359 final */ OJ C 262E , 29.10.2002, p. 325–335)
- [Original text](#)

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 **on the deliberate release into the environment of genetically modified organisms** and repealing Council Directive 90/220/EEC - Commission Declaration, OJ L 106, 17.4.2001, p. 1–39, CELEX number: 32001L0018

- Proposal (**Proposal for a European Parliament and Council Directive** amending Directive 90/220/EEC **on the deliberate release into the environment of genetically modified organisms**, COM/98/0085 final - COD 98/0072, OJ C 139, 4.5.1998, p. 1, CELEX number: 51998PC0085)
- Amended proposal (**Amended proposal** for a European Parliament and Council Directive amending Directive 90/220/EEC **on the deliberate release into the environment of genetically modified organisms**, COM/99/0139 final - COD 98/0072, OJ C 139, 19.5.1999, p. 7, CELEX number: 51999PC0139)
- Original text
- Consolidated text
- Document summary
- Original text

96/134/EC: Commission Decision of 16 January 1996 amending Decision 91/448/EEC concerning guidelines for classification referred to in Article 4 of Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms (Text with EEA relevance), OJ L 31, 9.2.1996, p. 25–27, CELEX number: 31996D0134

- Original text

93/572/EEC: Commission Decision of 19 October 1993 concerning the placing on the market of a product containing genetically modified organisms pursuant to Article 13 of Council Directive 90/220/EEC, OJ L 276, 9.11.1993, p. 16–17, CELEX number: 31993D0572

- Original text

91/596/EEC: Council Decision of 4 November 1991 concerning the Summary Notification Information Format referred to in Article 9 of Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, OJ L 322, 23.11.1991, p. 1–16, CELEX number: 31991D0596

- Proposal (Proposal For A Council Decision Concerning The Summary Notification Information Format Referred To In Article 9 Of Directive 90/220/Eec/* Com/91/282final */)
- Original text
- Consolidated text

III. Medical Devices (MD)

1) Medical devices

Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose (Text with EEA relevance), C/2022/8638, OJ L 311, 2.12.2022, p. 94–96, CELEX 32022R2347

- [Original text](#)

Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (Text with EEA relevance), C/2022/8626, OJ L 311, 2.12.2022, p. 60–93, CELEX 32022R2346

- [Original text](#)

Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards **harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment**, C/2022/9, OJ L 1, 5.1.2022, p. 11–13, CELEX number: 32022D0006

- [Original text](#)

Commission Implementing Regulation (EU) 2021/2226 of 14 December 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices, C/2021/8984, OJ L 448, 15.12.2021, p. 32–38, CELEX number: 32021R2226

- [Original text](#)

Commission Implementing Regulation (EU) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the **European Database on Medical Devices (Eudamed)**, C/2021/8447, OJ L 426, 29.11.2021, p. 9–15, CELEX number: 32021R2078

- [Original text](#)

Commission Delegated Directive (EU) 2021/1978 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or

refurbishment of medical devices (Text with EEA relevance), C/2021/5866, OJ L 402, 15.11.2021, p. 65–68, CELEX number: 32021L1978

- [Original text](#)

Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council, C/2021/5210, OJ L 256, 19.7.2021, p. 100–102, CELEX number: 32021D1182

- [Original text](#)

Commission Implementing Decision (EU) 2021/611 of 14 April 2021 amending Implementing Decision (EU) 2020/438 as regards harmonised standards on biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products and clinical investigation of medical devices for human subjects, C/2021/2434, OJ L 129, 15.4.2021, p. 158–160, CELEX number: 32021D0611

- [Original text](#)

Commission Implementing Decision (EU) 2021/610 of 14 April 2021 amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment, C/2021/2439, OJ L 129, 15.4.2021, p. 153–157, CELEX number: 32021D0610

- [Original text](#)

Commission Implementing Decision (EU) 2021/609 of 14 April 2021 amending Implementing Decision (EU) 2020/439 as regards harmonised standards on packaging for terminally sterilised medical devices and sterilisation of health care products, C/2021/2432, OJ L 129, 15.4.2021, p. 150–152, CELEX number: 32021D0609

- [Original text](#)

Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (Text with EEA relevance), OJ L 130, 24.4.2020, p. 18–22, CELEX number: 32020R0561

- [Proposal \(Proposal for a Regulation](#) of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of

application of certain of its provisions (Text with EEA relevance), COM(2020) 144 final, 2020/0060(COD)

- [Original text](#)

Commission Implementing Decision (EU) 2020/439 of 24 March 2020 on the harmonised standards for in vitro diagnostic medical devices drafted in support of Directive 98/79/EC of the European Parliament and of the Council, C/2020/1903, OJ L 90I, 25.3.2020, p. 33–39, CELEX number: 32020D0439

- [Original text](#)
- [Consolidated text](#)

Commission Implementing Decision (EU) 2020/438 of 24 March 2020 on the harmonised standards for active implantable medical devices drafted in support of Council Directive 90/385/EEC, C/2020/1902, OJ L 90I, 25.3.2020, p. 25–32, CELEX number: 32020D0438

- [Original text](#)
- [Consolidated text](#)

Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC, C/2020/1901, OJ L 90I, 25.3.2020, p. 1–24, CELEX number: 32020D0437

- [Original text](#)
- [Consolidated text](#)

Commission Implementing Decision (EU) 2019/1396 of 10 September 2019 laying down the rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the designation of expert panels in the field of medical devices (Text with EEA relevance.), C/2019/6414, OJ L 234, 11.9.2019, p. 23–30, CELEX number: 32019D1396

- [Original text](#)

Commission Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices (Text with EEA relevance.), C/2019/4068, OJ L 149, 7.6.2019, p. 73–75, CELEX number: 32019D0939

- [Original text](#)

Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under

Regulation (EU) 2017/746 of the European Parliament and of the Council (Text with EEA relevance.), C/2017/7779, OJ L 309, 24.11.2017, p. 7–17, CELEX number: 32017R2185

- [Original text](#)

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 **on medical devices**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance), OJ L 117, 5.5.2017, p. 1–175, CELEX number: 32017R0745

- [Proposal \(Proposal for a Regulation of the European Parliament and the Council on medical devices](#), and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, COM/2012/0542 final, 2012/0266 (COD), CELEX number: 52012PC0542)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices Text with EEA relevance, OJ L 253, 25.9.2013, p. 8–19, CELEX number: 32013R0920

- [Original text](#)
- [Consolidated text](#)

Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices Text with EEA relevance, OJ L 72, 10.3.2012, p. 28–31, CELEX number: 32012R0207

- [Original text](#)

2010/227/: **Commission Decision** of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (notified under document C(2010) 2363) (Text with EEA relevance), OJ L 102, 23.4.2010, p. 45–48, CELEX number: 32010D0227

- [Original text](#)

Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (Text with EEA relevance), OJ L 210, 12.8.2005, p. 41–43, CELEX number: 32005L0050

- [Original text](#)

Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (Text with EEA relevance), OJ L 28, 4.2.2003, p. 43–44, CELEX number: 32003L0012

- [Original text](#)

2) In vitro diagnostic MD

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 **on in vitro diagnostic medical devices** and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance), OJ L 117, 5.5.2017, p. 176–332, CELEX number: 32017R0746

- [Proposal](#) (**Proposal for a Regulation** of the European Parliament and of the Council **on in vitro diagnostic medical devices**, /* COM/2012/0541 final - 2012/0267 (COD) */), CELEX number: 52012PC0541
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

2011/869/EU: Commission Decision of 20 December 2011 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (notified under document C(2011) 9398) Text with EEA relevance, OJ L 341, 22.12.2011, p. 63–64, CELEX number: 32011D0869

- [Original text](#)

2009/886/EC: Commission Decision of 27 November 2009 amending Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices (notified under document C(2009) 9464) (Text with EEA relevance), OJ L 318, 4.12.2009, p. 25–40, CELEX number: 32009D0886

- [Original text](#)
- [Consolidated text](#)

2002/364/EC: Commission Decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (Text with EEA relevance) (notified under document number C(2002) 1344), OJ L 131, 16.5.2002, p. 17–30, CELEX number: 32002D0364

- [Original text](#)
- [Consolidated text](#)

2002/65/EC: Commission Decision of 25 January 2002 on the national provisions concerning HIV testing kits notified under Article 95(4) of the EC Treaty by the United Kingdom as regards Directive 98/79/EC on in vitro diagnostic medical devices (Text with EEA

relevance) (notified under document number C(2002) 297), OJ L 25, 29.1.2002, p. 47–48, CELEX 32002D0065

- [Original text](#)

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 **on in vitro diagnostic medical devices**, OJ L 331, 7.12.1998, p. 1–37, CELEX number: 31998L0079

- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

3) Implantable MD

Commission Regulation (EU) No 722/2012 of 8 August 2012 **concerning particular requirements** as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC **with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin** (Text with EEA relevance), OJ L 212, 9.8.2012, p. 3–12, CELEX number: 32012R0722

- [Original text](#)

IV. Medicinal products (MP)

1) Innovative medicines / High-technology MP

Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, ST/12156/2021/INIT, OJ L 427, 30.11.2021, p. 17–119, CELEX 32021R2085

- [Original text](#)

Council Directive 93/41/EEC of 14 June 1993 repealing Directive 87/22/EEC **on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology**, OJ L 214, 24.8.1993, p. 40–40, CELEX number: 31993L0041

- [Proposal](#) (**Proposal for a Council Directive** repealing Directive 87/22/EEC **on the approximation of national measures relating to the placing on the market of high-technology medicinal products particularly those derived from**

biotechnology, COM/90/283 final - SYN 312, OJ C 330, 31.12.1990, p. 32–32,
CELEX number: 51990PC0283(04))

- [Original text](#)

2) Advanced therapy MP

Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code **relating to medicinal products for human use as regards advanced therapy medicinal products** (Text with EEA relevance), OJ L 242, 15.9.2009, p. 3–12, CELEX number: 32009L0120

- [Original text](#)

Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation (EC) No 1394/2007 of the European Parliament and of the Council **with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises** (Text with EEA relevance), OJ L 194, 25.7.2009, p. 7–10, CELEX number: 32009R0668

- [Original text](#)

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 **on advanced therapy medicinal products** and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance), OJ L 324, 10.12.2007, p. 121–137, CELEX number: 32007R1394

- [Proposal \(Proposal for a Regulation](#) of the European Parliament and of the Council **on advanced therapy medicinal products** and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (SEC (2005) 1444), COM/2005/0567 final - COD 2005/0227, CELEX number: 52005PC0567)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

3) Medicinal Products for paediatric use

Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 amending Regulation 1901/2006 **on medicinal products for paediatric use** (Text with EEA relevance), OJ L 378, 27.12.2006, p. 20–21, CELEX number: 32006R1902

- [Proposal \(Proposal for a Regulation](#) of the European Parliament and of the Council amending Regulation xxx/2006 **on medicinal products for paediatric use** and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, COM/2006/0640 final - COD 2006/0207, CELEX number: 52006PC0640)
- [Original text](#)

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 **on medicinal products for paediatric use** and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance), OJ L 378, 27.12.2006, p. 1–19, CELEX number: 32006R1901

- [Proposal \(Proposal for a Regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation \(EEC\) No 1768/92, Directive 2001/83/EC and Regulation \(EC\) No 726/2004 {SEC \(2004\) 1144}, COM/2004/0599 final - COD 2004/0217, CELEX number: 52004PC0599\)](#)
- [Amended proposal \(Amended proposal for a Regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation \(EEC\) No 1768/92, Directive 2001/83/EC and Regulation \(EC\) No 726/2004 \(presented by the Commission pursuant to Article 250 \(2\) of the EC Treaty\), COM/2005/0577 final - COD 2004/0217, CELEX number: 52005PC0577\)](#)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

4) Orphan medicinal products

Commission Regulation (EC) No 847/2000 of 27 April 2000 **laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'**, OJ L 103, 28.4.2000, p. 5–8, CELEX number: 32000R0847

- [Original text](#)
- [Consolidated text](#)

Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 **on orphan medicinal products**, OJ L 18, 22.1.2000, p. 1–5, CELEX number: 32000R0141

- [Proposal \(Proposal for a European Parliament and Council Regulation \(EC\) on orphan medicinal products, COM/98/0450 final - COD 98/0240, OJ C 276, 4.9.1998, p. 7, CELEX number: 51998PC0450\)](#)
- [Amended proposal \(Amended proposal for a European Parliament and Council Regulation \(EC\) on orphan medicinal products, COM/99/0298 final - COD 98/0240, OJ C 177E, 27.6.2000, p. 1–10, CELEX number: 51999PC0298\)](#)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

5) Clinical trials

a) *Clinical trials of MP with GMOs for COVID-19*

Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 **on the conduct of clinical trials with and supply of medicinal products for human use**

containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19), PE/28/2020/REV/1, OJ L 231, 17.7.2020, p. 12–16, CELEX number: 32020R1043

- **Proposal (Proposal for a Regulation of the European Parliament and of the Council on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease, COM/2020/261 final, CELEX number: 52020PC0261)**
- **Original text**

b) Clinical trials

Commission Delegated Regulation (EU) 2022/2239 of 6 September 2022 amending Regulation (EU) No 536/2014 of the European Parliament and of the Council as regards labelling requirements for unauthorised investigational and unauthorised auxiliary medicinal products for human use (Text with EEA relevance), C/2022/6240, OJ L 294, 15.11.2022, p. 5–7, CELEX 32022R2239

- **Original text**

Commission Decision (EU) 2021/1240 of 13 July 2021 on the compliance of the EU portal and the EU database for clinical trials of medicinal products for human use with the requirements referred to in Article 82(2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council (Text with EEA relevance), C/2021/5063, OJ L 275, 31.7.2021, p. 1–2, CELEX number: 32021D1240

- **Original text**

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance, OJ L 158, 27.5.2014, p. 1–76, CELEX number: 32014R0536

- **Proposal (Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, COM/2012/0369 final - 2012/0192 (COD), CELEX number: 52012PC0369)**
- **Original text**
- **Consolidated text**
- **Document summary**

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical

trials on medicinal products for human use, OJ L 121, 1.5.2001, p. 34–44, CELEX number: 32001L0020

- Proposal (**Proposal for a European Parliament and Council Directive** on the approximation of provisions laid down by law, regulation or administrative action **relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use**, COM/97/0369 final - COD 97/0197, OJ C 306, 8.10.1997, p. 9–15, CELEX number: 51997PC0369)
- Amended proposal (**Amended proposal for a European Parliament and Council Directive** on the approximation of the laws, regulations and administrative provisions of the Member States **relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use**, COM/99/0193 final - COD 97/0197, OJ C 161, 8.6.1999, p. 5, CELEX number: 51999PC0193)
- Original text
- Consolidated text
- Document summary

c) Investigational MP

Commission Directive 2005/28/EC of 8 April 2005 **laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products**, OJ L 91, 9.4.2005, p. 13–19, CELEX number: 32005L0028

- Original text

6) Community Code MP

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC **on the Community code relating to medicinal products for human use** (Text with EEA relevance), OJ L 136, 30.4.2004, p. 34–57, CELEX number: 32004L0027

- Proposal (**Proposal for a Directive** of the European Parliament and of the Council amending Directive 2001/83/EC **on the Community code relating to medicinal products for human use** (COM (2001/0404 final - 2001/0253(COD))), OJ C 75E, 26.3.2002, p. 216–233, CELEX number: 52001PC0404(02))
- Original text

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council **on the Community code relating to medicinal products for human use** (Text with EEA relevance), OJ L 159, 27.6.2003, p. 46–94, CELEX number: 32003L0063

- Original text

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 **on the Community code relating to medicinal products for human use**, OJ L 311, 28.11.2001, p. 67–128, CELEX number: 32001L0083

- [Proposal \(Proposal for a European Parliament and Council Directive on the Community code relating to medicinal products for human use - \(codified version\)](#), COM/99/0315 final - COD 99/0134, CELEX number: 51999PC0315)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

7) European Medicines Agency (EMA)

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (Text with EEA relevance), PE/76/2021/REV/1, OJ L 20, 31.1.2022, p. 1–37, CELEX 32022R0123

- [Original text](#)

Commission Regulation (EU) 2020/422 of 19 March 2020 **amending Council Regulation (EC) No 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate with effect from 1 April 2020**, OJ L 84, 20.3.2020, p. 11–14, CELEX number: 32020R0422

- [Original text](#)

Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 **laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance), PE/44/2018/REV/1, OJ L 4, 7.1.2019, p. 24-42, CELEX number: 32019R0005

- [Proposal \(Proposal for a Regulation of the European Parliament and of the Council amending Regulation \(EC\) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency](#), COM/2014/0557 final - 2014/0256 (COD), CELEX number: 52014PC0557)
- [Original text](#)

Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 **on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use** (Text with EEA relevance), OJ L 189, 27.6.2014, p. 112–127, CELEX number: 32014R0658

- [Proposal](#) (**Proposal for a Regulation of the European Parliament and of the Council on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use**, COM/2013/0472 final - 2013/0222 (COD), CELEX number: 52013PC0472)
- [Original text](#)
- [Consolidated text](#)

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 **laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency** (Text with EEA relevance), OJ L 136, 30.4.2004, p. 1–33, CELEX number: 32004R0726

- [Proposal](#) (**Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products** (COM (2001) 404 final — 2001/0252(COD)), OJ C 75E, 26.3.2002, p. 189–215, CELEX number: 52001PC0404(01))
- [Modified proposal](#) (**Modified proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision and pharmacovigilance of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products** (presented by the Commission pursuant to Article 250 (2) of the EC Treaty), COM/2002/0735 final - COD 2001/0252, CELEX number: 52002PC0735)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

Council Regulation (EC) No 297/95 of 10 February 1995 **on fees payable to the European Agency for the Evaluation of Medicinal Products**, OJ L 35, 15.2.1995, p. 1–5, CELEX number: 31995R0297

- [Proposal](#) (Proposal for a **Council Regulation (EC) on fees payable to the European Medicines Evaluation Agency**, COM/94/167 final, OJ C 398, 31.12.1994, p. 20–23, CELEX number: 51994PC0167)
- [Original text](#)
- [Consolidated text](#)

8) Falsified MP

Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, **as regards the prevention of the entry into the legal supply chain of falsified medicinal products** (Text with EEA relevance), OJ L 174, 1.7.2011, p. 74-87, CELEX number: 32011L0062

- [Proposal](#) (**Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their**

identity, history or source {SEC (2008) 2674} {SEC (2008) 2675}, COM/2008/0668 final - COD 2008/0261, CELEX number: 52008PC0668)

- [Original text](#)

9) Manufacturing and packaging

Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council **as regards the principles and guidelines of good manufacturing practice for medicinal products for human use** (Text with EEA relevance), C/2017/6127, OJ L 238, 16.9.2017, p. 44–50, CELEX number: 32017L1572

- [Original text](#)

Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by **specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections** (Text with EEA relevance), C/2017/3368, OJ L 238, 16.9.2017, p. 12–21, CELEX number: 32017R1569

- [Original text](#)

Commission delegated regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the **safety features appearing on the packaging of medicinal products for human use**, OJ L 32, 9.2.2016, pp. 1–27.

- [Original text](#)
- [Consolidated text](#)

Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of **good manufacturing practice for active substances** for medicinal products for human use Text with EEA relevance, OJ L 337, 25.11.2014, p. 1–7, CELEX number: 32014R1252

- [Original text](#)

Commission Directive 2005/28/EC of 8 April 2005 **laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products** (Text with EEA relevance), OJ L 91, 9.4.2005, p. 13–19, CELEX number: 32005L0028

- [Original text](#)

10) Marketing authorisations/patent

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the supplementary protection certificate for medicinal products (recast), 27.4.2023, COM/2023/231 final, CELEX 52023PC0231

- [Proposal](#)

Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the **supplementary protection certificate for medicinal products** (Text with EEA relevance.) PE/52/2019/REV/1, OJ L 153, 11.6.2019, p. 1–10.

- [Proposal](#)
- [Original text](#)

Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, **as regards variations to the terms of marketing authorisations for medicinal products** (Text with EEA relevance), OJ L 168, 30.6.2009, p. 33–34, CELEX number: 32009L0053

- [Proposal](#) (**Proposal for a Directive** of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC **as regards variations to the terms of marketing authorisations for medicinal products** {SEC (2008) 273} {SEC (2008) 274}, COM/2008/0123 final - COD 2008/0045, CELEX number: 52008PC0123)
- [Original text](#)

Commission Regulation (EC) No 1234/2008 of 24 November 2008 **concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products** (Text with EEA relevance), OJ L 334, 12.12.2008, p. 7–24, CELEX number: 32008R1234

- [Original text](#)
- [Consolidated text](#)

Commission Regulation (EC) No 507/2006 of 29 March 2006 **on the conditional marketing authorisation for medicinal products for human use** falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (Text with EEA relevance), OJ L 92, 30.3.2006, p. 6–9, CELEX number: 32006R0507

- [Original text](#)

11) Pharmacovigilance

Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 **on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring** (Text with EEA relevance), OJ L 65, 8.3.2013, p. 17–18, CELEX number: 32013R0198

- [Original text](#)

Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC **as regards pharmacovigilance** (Text with EEA relevance), OJ L 299, 27.10.2012, p. 1–4, CELEX number: 32012L0026

- [Proposal \(Proposal for a Directive](#) of the European Parliament and of the Council amending Directive 2001/83/EC **as regards pharmacovigilance**, COM/2012/052 final - 2012/0025 (COD), CELEX number: 52012PC0052)
- [Original text](#)

Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 **as regards pharmacovigilance** (Text with EEA relevance), OJ L 316, 14.11.2012, p. 38–40, CELEX number: 32012R1027

- [Proposal \(Proposal for a Regulation](#) of the European Parliament and of the Council amending Regulation (EC) No 726/2004 **as regards pharmacovigilance**, COM/2012/051 final - 2012/0023 (COD), CELEX number: 52012PC0051)
- [Original text](#)

Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 **on the performance of pharmacovigilance activities** provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (Text with EEA relevance), OJ L 159, 20.6.2012, p. 5–25, CELEX number: 32012R0520

- [Original text](#)

Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, **as regards pharmacovigilance**, Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance), OJ L 348, 31.12.2010, p. 74–99, CELEX number: 32010L0084

- [Proposal \(Proposal for a Directive](#) of the European Parliament and of the Council amending, **as regards pharmacovigilance**, Directive 2001/83/EC **on the Community code relating to medicinal products for human use** {SEC (2008) 2670} {SEC(2008) 2671}, COM/2008/0665 final - COD 2008/0260, CELEX number: 52008PC0665)
- [Original text](#)
- [Consolidated text](#)

Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, **as regards pharmacovigilance of medicinal products for human use**, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and

establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (Text with EEA relevance), OJ L 348, 31.12.2010, p. 1–16, CELEX number: 32010R1235

- [Proposal \(Proposal for a Regulation of the European Parliament and of the Council amending, as regards pharmacovigilance of medicinal products for human use, Regulation \(EC\) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency {SEC \(2008\) 2670} {SEC \(2008\) 2671}, COM/2008/0664 final - COD 2008/0257, CELEX number: 52008PC0664\)](#)
- [Original text](#)
- [Consolidated text](#)

V. Other legislations

1) EU 4 Health

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('**EU4Health Programme**') for the period **2021-2027**, and repealing Regulation (EU) No 282/2014, OJ L 107, 26.3.2021, pp. 1–29, CELEX number: 32021R0522

- [Proposal](#)
- [Original text](#)

2) Research and Innovation

Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, 2021/C 393 I/02C/2021/6712, OJ C 393I , 29.9.2021, p. 3-8, CELEX 32021D0929(02)

- [Original text](#)

Regulation (EU) 2021/819 of the European Parliament and of the Council of 20 May 2021 on the European Institute of Innovation and Technology (recast), OJ L 189, 28.5.2021, p. 61–90, CELEX 32021R0819

- [Original text](#)

Decision (EU) 2021/820 of the European Parliament and of the Council of 20 May 2021 on the Strategic Innovation Agenda of the European Institute of Innovation and Technology (EIT) 2021-2027: Boosting the Innovation Talent and Capacity of Europe and repealing Decision No 1312/2013/EU (Text with EEA relevance), PE/9/2021/REV/1, OJ L 189, 28.5.2021, p. 91–118, CELEX 32021D0820

- [Original text](#)

Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing **Horizon Europe** – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, OJ L 170, 12.5.2021, p. 1–68, CELEX number: 32021R0695.

- [Original text](#)
- [Document summary](#)

Council Decision (EU) 2021/764 of 10 May 2021 establishing the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation, and repealing Decision 2013/743/EU, ST/8967/2020/INIT, OJ L 167I , 12.5.2021, p. 1–80, CELEX 32021D0764

- [Original text](#)

Decision No 554/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in the Active and Assisted Living Research and Development Programme jointly undertaken by several Member States, OJ L 169, 7.6.2014, p. 14-26, CELEX 32014D0554

- [Original text](#)

2013/743/EU: Council Decision of 3 December 2013 establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC Text with EEA relevance, OJ L 347, 20.12.2013, p. 965–1041, CELEX 32013D0743

- [Original text](#)

Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the regions Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, COM/2021/576 final, CELEX 52021DC0576

- [Original text](#)

3) Price and reimbursement

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on **health technology assessment** and amending Directive 2011/24/EU, *OJ L 458*, 22 December 2021, p. 1–32, CELEX number: 32021R2282

- [Proposal \(Proposal for a Regulation](#) of the European Parliament and of the Council on **health technology assessment** and amending Directive 2011/24/EU, COM/2018/051 final - 2018/018 (COD), CELEX number: 52018PC0051)
- [Original text](#)

Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 **on the coordination of social security systems** (Text with relevance for the EEA and for Switzerland), *OJ L 166*, 30.4.2004, p. 1–123, CELEX number: 32004R0883

- [Proposal \(Proposal for a Council Regulation \(EC\) on coordination of social security systems](#), COM/98/0779 final - AVC 98/0360, *OJ C 38*, 12.2.1999, p. 10, CELEX number: 51998PC0779)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

Amended proposal for a Directive of the European Parliament and of the Council **on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems**, COM/2013/0168 final - 2012/0035 (COD), CELEX number: 52013PC0168

- [Amended proposal](#)

Council Directive 89/105/EEC of 21 December 1988 **relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems**, *OJ L 40*, 11.2.1989, p. 8–11, CELEX number: 31989L0105

- [Proposal \(Proposal for a Council Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of the national health insurance system](#), COM/86/765 final - SYN 79, *OJ C 17*, 23.1.1987, p. 6–9, CELEX number: 51986PC0765)
- [Amended proposal \(Amended proposal for a Council Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within in the scope of national the health insurance system](#), COM/88/231 final - SYN 79, *OJ C 129*, 18.5.1988, p. 14–18, CELEX number: 51988PC0231)
- [Original text](#)
- [Document summary](#)

4) Cross-border patients' rights

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 **on the application of patients' rights in cross-border healthcare**, OJ L 88, 4.4.2011, p. 45–65, CELEX number: 32011L0024

- Proposal (**Proposal for a Directive** of the European Parliament and of the Council **on the application of patients' rights in cross-border healthcare** {SEC (2008) 2163} {SEC (2008) 2164} {SEC (2008) 2183}, COM/2008/0414 final - COD 2008/0142, CELEX number: 52008PC0414)
- Original text
- Consolidated text
- Document summary

5) Legal protection of biotechnological inventions

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 **on the legal protection of biotechnological inventions**, OJ L 213, 30.7.1998, p. 13–21, CELEX number: 31998L0044

- Proposal 1 (**Proposal for a Council Directive on the legal protection of biotechnological inventions**, COM/88/496 final - SYN 159 OF 17/10/88, OJ C 10, 13.1.1989, p. 3–8, CELEX number: 51988PC0496)
- Amended proposal 1 (**Amended proposal for a Council Directive on the legal protection of biotechnological inventions**, COM/92/589 final - SYN 159, OJ C 44, 16.2.1993, p. 36–50, CELEX number: 51992PC0589)
- Proposal 2 (**Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions**, COM/95/0661 final – COD 95/0350, OJ C 296, 8.10.1996, p. 4–10, CELEX number: 51995PC0661)
- Amended Proposal 2 (**Amended proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions**, COM(97) 446 final, 95/ 0350 (COD), Brussels, 29.08.1997)
- Original text
- Document summary

6) Creation of unitary patent protection

Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 **implementing enhanced cooperation in the area of the creation of unitary patent protection**, OJ L 361, 31.12.2012, p. 1–8, CELEX number: 32012R1257

- Proposal (**Proposal for a Regulation of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of unitary patent protection**, COM/2011/0215 final - 2011/0093 (COD), CELEX number: 52011PC0215)
- Original text
- Document summary

Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing **enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements**, OJ L 361, 31.12.2012, p. 89–92, CELEX number: 32012R1260.

- [Original text](#)
- [Document summary](#)

Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1–40, CELEX number:42013A0620(01)

- [Original text](#)
- [Document summary](#)

Council Decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection, OJ L 76, 22.3.2011, p. 53–55, CELEX 32011D0167

- [Original text](#)

Agreement 89/695/EEC relating to Community patents - Done at Luxembourg on 15 December 1989, OJ L 401, 30.12.1989, p. 1–27, CELEX 41989A06995(01)

- [Original text](#)

7) Personal data

Proposal for a regulation of the European Parliament and of the Council on the European health data space, COM/2022/197 Final, CELEX 52022PC0197

- [Proposal](#)

Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending certain Union legislative acts, 2021/0106(COD), Doc. ST_15698_2022_INIT

- [Proposal](#)

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 **on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data**, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (Text with EEA relevance.), PE/31/2018/REV/1, OJ L 295, 21.11.2018, p. 39–98, CELEX number: 32018R1725

- [Proposal](#) (**Proposal for a Regulation** of the European Parliament and of the Council **on the protection of individuals with regard to the processing of personal data**)

by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, COM/2017/08 final - 2017/02 (COD), CELEX number: 52017PC0008)

- [Original text](#)
- [Document summary](#)

Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ L 119, 4.5.2016, p. 89–131, CELEX 32016L0680

- [Original text](#)

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), OJ L 119, 4.5.2016, p. 1–88, CELEX number: 32016R0679

- [Proposal \(Proposal for a Regulation](#) of the European Parliament and of the Council **on the protection of individuals with regard to the processing of personal data and on the free movement of such data** (General Data Protection Regulation), COM/2012/011 final - 2012/0011 (COD), CELEX number: 52012PC0011)
- [Proposal \(Proposal for a Directive](#) of the European Parliament and of the Council **on the protection of individuals with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and the free movement of such data**, COM/2012/010 final - 2012/0010 (COD), CELEX number: 52012PC0010)
- [Original text](#)
- [Consolidated text](#)
- [Document summary](#)

Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, JO L 77 du 27.3.1996, p. 20–28, CELEX 31996L0009

- [Original text](#)

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Annex 2.b to Deliverable D.4.7

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II. Guidelines applicable to all ATMPs or some ATMPs

A. Guidelines

1. Guidelines specific to ATMPs

- EMA, CAT, Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials, EMA/CAT/852602/2018, 31 January 2019, <https://www.ema.europa.eu/en/guideline-quality-non-clinical-clinical-requirements-investigational-advanced-therapy-medicinal>
- EMA, CHMP, Guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products, EMEA/149995/2008, 20 November 2008, UNDER REVISION, <https://www.ema.europa.eu/en/guideline-safety-efficacy-follow-risk-management-advanced-therapy-medicinal-products>
- EMA, CAT, Risk-based approach according to Annex I, part IV of Directive 2001/83/EC applied to Advanced Therapy Medicinal Products, EMA/CAT/CPWP/686637/2011, 11 February 2013, <https://www.ema.europa.eu/en/risk-based-approach-according-annex-i-part-iv-directive-200183ec-applied-advanced-therapy-medicinal>
- European Commission, Guidelines on Good Manufacturing Practices specific to ATMPs, C(2017) 7694 final, 22 November 2017, EMA: <https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/support-advanced-therapy-developers#gmp-requirements-section>
 EC: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en#part-iv---gmp-requirements-for-advanced-therapy-medicinal-products
https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-4/2017_11_22_guidelines_gmp_for_atmps.pdf
- European Commission, Guidelines on Good Clinical Practices specific to ATMPs, C(2019) 7140 final, 10 October 2019, EMA: <https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/support-advanced-therapy-developers#gcp-requirements-section>

EC: https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-10_en#set-of-documents-applicable-to-clinical-trials-authorized-under-directive-200120ec

https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-10/atmp_guidelines_en.pdf

- EMA, CAT, Procedural advice on the certification of quality and non-clinical data for SMEs developing ATMPs, EMA/CAT/418458/2008/rev., 27 September 2016, <https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/advanced-therapy-development/certification-procedures-micro-small-medium-sized-enterprises-smes#procedural-advice-section>
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-certification-quality-non-clinical-data-small-medium-sized-enterprises-developing_en.pdf
- EMA, CAT, Guideline on the minimum quality and non-clinical data for certification of ATMPs, EMA/CAT/486831/2008/corr., 15 October 2010, <https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/advanced-therapy-development/certification-procedures-micro-small-medium-sized-enterprises-smes#guideline-on-the-minimum-quality-and-non-clinical-data-section>
https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-minimum-quality-non-clinical-data-certification-advanced-therapy-medicinal-products_en.pdf

2. Guidelines for medicinal products in general

- EMA, Guideline on quality documentation for medicinal products when used with a medical device, 22 July 2021, EMA/CHMP/QWP/BWP/259165/2019, <https://www.ema.europa.eu/en/quality-documentation-medicinal-products-when-used-medical-device-scientific-guideline>
- EMA, CHMP, Guideline on strategies to identify and mitigate risks for first-in-human clinical trials within investigational medicinal products EMEA/CHMP/SWP/28367/07 Rev.1, 20 July 2017, <https://www.ema.europa.eu/en/strategies-identify-mitigate-risks-first-human-early-clinical-trials-investigational-medicinal>
- EMA, CHMP, Guideline on non-clinical tolerance testing of medicinal products, EMA/CHMP/SWP/2145/00 Rev.1 Corr. 1, 22 October 2015, <https://www.ema.europa.eu/en/non-clinical-local-tolerance-testing-medicinal-products-scientific-guideline>
- EMA, CHMP, Guideline on repeated dose toxicity, CPMP/SWP/1042/99 Rev. 1 Corr., 18 March 2010, <https://www.ema.europa.eu/en/repeated-dose-toxicity>
- Clinical Trial Facilitation Group, Recommendations related to contraception and pregnancy testing in clinical trials Version 1.1, 21 September 2020, https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2020_09_HMA_CTFG_Contraception_guidance_Version_1.1_updated.pdf
<https://www.hma.eu/about-hma/working-groups/clinical-trials-facilitation-and-coordination-group.html>
- EMA, Guidelines on Good Pharmacovigilance Practices, <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/good-pharmacovigilance-practices>
- European Commission, EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, ENTR/F/2/AM/an D(2010) 3374, Annex 13 -

Manufacture of investigational medicinal products, 3 February 2010,
https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-4/2009_06_annex13.pdf

https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en#annexes

- European Commission, EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Ref. Ares(2015)4234460, Annex 16 - Certification by a qualified person and batch release, 12 October 2015,
https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-4/v4_an16_201510_en.pdf
https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en#annexes
- EMA, CHMP, CVMP, Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches, EMA/CHMP/CVMP/JEG-3Rs/450091/2012, 15 December 2016, <https://www.ema.europa.eu/en/regulatory-acceptance-3r-replacement-reduction-refinement-testing-approaches>
- EMA, CHMP, CVMP, Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – report on actions taken, EMA/CHMP/CVMP/3Rs/677407/2015, 28 June 2018, <https://www.ema.europa.eu/en/review-update-ema-guidelines-implement-best-practice-regard-3rs-replacement-reduction-refinement>
- EMA, CHMP, CVMP, Guidance for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs, EMA/CHMP/CVMP/3Rs/94436/2014, 9 November 2017, <https://www.ema.europa.eu/en/guidance-individual-laboratories-transfer-quality-control-methods-validated-collaborative-trials>
- EMA, Heads of Medicines Agency, (EU innovation Network), Guidance for applicants on simultaneous national scientific advice (SNSA) phase 2 pilot (from October 2022) – Optimised process, EMA/896928/2022, 22 November 2022, https://www.ema.europa.eu/documents/other/guidance-applicants-simultaneous-national-scientific-advice-snsa-phase-2-pilot-october-2022_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#eu-innovation-network-section>
- EMA, Heads of Medicines Agency, (EU innovation Network), Guidance for applicants on Simultaneous National Scientific Advice (SNSA) Briefing book format and content, EMA/896929/2022, 22 November 2022, https://www.ema.europa.eu/documents/other/guidance-applicants-simultaneous-national-scientific-advice-snsa-briefing-book-format-content_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#eu-innovation-network-section>
- EMA, Human Medicines Division, European Medicines Agency Guidance for applicants seeking access to PRIME scheme, EMA/191104/2015, 10 July 2023, https://www.ema.europa.eu/documents/other/european-medicines-agency-guidance-applicants-seeking-access-prime-scheme_en-0.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines#key-benefits-for-applicants-section>
- EMA, CHMP, Toolbox guidance on scientific elements and regulatory tools to support quality data packages for PRIME marketing authorisation applications, EMA/CHMP/BWP/QWP/IWG/694114/2019, 22 April 2022, <https://www.ema.europa.eu/en/toolbox-guidance-scientific-elements-regulatory-tools-support-quality-data-packages-prime-certain>

3. Guidelines for medicinal products containing genetically modified cells

- EMA, CAT, Quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells, EMA/CAT/GTWP/671639/2008 Rev. 1 – corr, 12 November 2020, <https://www.ema.europa.eu/en/quality-non-clinical-clinical-aspects-medicinal-products-containing-genetically-modified-cells>
- EMA, CAT, Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells, EMA/CAT/CHMP/158266/2021, 10 May 2022, <https://www.ema.europa.eu/en/guideline-core-smpc-labelling-package-leaflet-advanced-therapy-medicinal-products-atmps-containing>

4. Guidelines for Biologicals: drug product

- EMA, CHMP, Guideline on environmental risk assessments for medicinal products consisting of, or containing, genetically modified organisms (GMOs), EMEA/CHMP/BWP/473191/2006, 11 December 2006, <https://www.ema.europa.eu/en/environmental-risk-assessments-medicinal-products-containing-consisting-genetically-modified>
- EMA, CHMP, Guideline on the use of bovine serum in the manufacture of human biological medicinal products, EMA/CHMP/BWP/457920/2012 rev 1, 30 May 2013, <https://www.ema.europa.eu/en/use-bovine-serum-manufacture-human-biological-medicinal-products>
- EMA, CHMP, Guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products, EMA/CHMP/BWP/814397/2011, 20 February 2014, <https://www.ema.europa.eu/en/use-porcine-trypsin-used-manufacture-human-biological-medicinal-products>

5. Guidelines for Biologicals: drug substance

- EMA, Quality of biological active substances produced by transgene expression in animals, 10 June 2013 <https://www.ema.europa.eu/en/quality-biological-active-substances-produced-transgene-expression-animals-scientific-guideline>

6. Guidelines on quality excipients

- EMA, CHMP, Guideline on excipients in the dossier for application for marketing authorisation of a medicinal product, EMEA/CHMP/QWP/396951/2006, 19 June 2007, <https://www.ema.europa.eu/en/excipients-dossier-application-marketing-authorisation-medicinal-product>
- EMA, CHMP, Guideline on plasma-derived medicinal products, 21 July 2011, EMA/CHMP/BWP/706271/2010, <https://www.ema.europa.eu/en/plasma-derived-medicinal-products-scientific-guideline>

7. Guidelines and points to consider on safety and efficacy: biostatistics

- EMA, CHMP, Guideline on clinical trials in small populations, CHMP/EWP/83561/2005, 27 July 2006, <https://www.ema.europa.eu/en/clinical-trials-small-populations>
- EMA, CPMP, Points to consider on applications with 1. Meta-analyses; 2. One pivotal study, CPMP/EWP/2330/99, 31 May 2001, <https://www.ema.europa.eu/en/application-1-meta-analyses-2-one-pivotal-study>

8. ICH Guidelines on quality

- EMA, CPMP, ICH Q2 (R1) Validation of analytical procedures: text and methodology, CPMP/ICH/381/95, June 1995, <https://www.ema.europa.eu/en/ich-q2-r1-validation-analytical-procedures-text-methodology>
- EMA, CPMP, ICH Q5A (R1) Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin, CPMP/ICH/295/95, October 1997, UNDER REVISION (10 October 2022), <https://www.ema.europa.eu/en/ich-q5a-r1-quality-biotechnological-products-viral-safety-evaluation-biotechnology-products-derived>
- EMA, CPMP, ICH Q5C Stability testing of biotechnological/biological products, CPMP/ICH/138/95, July 1996, <https://www.ema.europa.eu/en/ich-q5c-stability-testing-biotechnologicalbiological-products>
- EMA, CPMP, ICH Q5D Derivation and characterisation of cell substrates used for production of biotechnological/biological products, CPMP/ICH/294/95, March 1998, <https://www.ema.europa.eu/en/ich-q5d-derivation-characterisation-cell-substrates-used-production-biotechnologicalbiological>
- EMA, CPMP, ICH Q5E Comparability of biotechnological/biological products, CPMP/ICH/5721/03, June 2005, <https://www.ema.europa.eu/en/ich-q5e-biotechnologicalbiological-products-subject-changes-their-manufacturing-process>
- EMA, CPMP, ICH Q6B Specifications: Test procedures and acceptance criteria for biotechnological/biological products, CPMP/ICH/365/96, September 1999, <https://www.ema.europa.eu/en/ich-q6b-specifications-test-procedures-acceptance-criteria-biotechnologicalbiological-products>
- EMA, CPMP, ICH Q7 Good manufacturing practice for active pharmaceutical ingredients, CPMP/ICH/4106/00, November 2000, <https://www.ema.europa.eu/en/ich-q7-good-manufacturing-practice-active-pharmaceutical-ingredients>
- EMA, CHMP, ICH Q8 (R2) Pharmaceutical development, CHMP/ICH/167068/04, 22 June 2017, <https://www.ema.europa.eu/en/ich-q8-r2-pharmaceutical-development>
- EMA, CHMP, ICH guideline Q9 (R1) on quality risk management - Step 5, EMA/CHMP/ICH/24235/2006, 3 February 2023, <https://www.ema.europa.eu/en/ich-q9-quality-risk-management>
- EMA, CHMP, ICH Q10 Pharmaceutical quality system, EMA/CHMP/ICH/214732/2007, September 2015, <https://www.ema.europa.eu/en/ich-q10-pharmaceutical-quality-system>

9. ICH Guidelines on Efficacy

- EMA, CPMP, ICH E1 The extent of population exposure to assess clinical safety, CPMP/ICH/375/95, June 1995, <https://www.ema.europa.eu/en/ich-e1-population-exposure-extent-population-exposure-assess-clinical-safety>
- EMA, CPMP, ICH E3 Structure and content of clinical study reports, CPMP/ICH/137/95, July 1996, <https://www.ema.europa.eu/en/ich-e3-structure-content-clinical-study-reports>
- EMA, CPMP, ICH E4 Dose response information to support drug registration, CPMP/ICH/378/95, November 1994, <https://www.ema.europa.eu/en/ich-e4-dose-response-information-support-drug-registration>
- EMA, CHMP, ICH E6 (R2) Good clinical practice Step 5, CPMP/ICH/135/95, 1 December 2016, UNDER REVISION (23 May 2023), <https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice>
- EMA, CPMP, ICH E7 Geriatrics, CPMP/ICH/379/95, March 1994, <https://www.ema.europa.eu/en/ich-e7-studies-support-special-populations-geriatrics>
- EMA, CPMP, ICH guideline E8 (R1) on general considerations for clinical studies – Step 5, EMA/CHMP/ICH/544570/1998, 14 October 2021, <https://www.ema.europa.eu/en/ich-e8-general-considerations-clinical-studies>
- EMA, CPMP, ICH guideline E10 on choice of control groups in clinical trials, CPMP/ICH/364/96, January 2001, <https://www.ema.europa.eu/en/ich-e10-choice-control-group-clinical-trials>
- EMA, CHMP, ICH E11 (1) Clinical investigation of medicinal products in the paediatric population, CPMP/ICH/2711/99, 1 September 2017, <https://www.ema.europa.eu/en/ich-e11r1-step-5-guideline-clinical-investigation-medicinal-products-pediatric-population>

10. ICH Guidelines on non-clinical development of medicinal products

- EMA, CPMP, ICH guideline M3 (R2) on non-clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals, EMA/CPMP/ICH/286/1995, December 2009, <https://www.ema.europa.eu/en/ich-m3-r2-non-clinical-safety-studies-conduct-human-clinical-trials-pharmaceuticals>
- EMA, CHMP, ICH guideline S2 (R1) on genotoxicity testing and data interpretation for pharmaceuticals intended for human use, EMA/CHMP/ICH/126642/2008, June 2012, <https://www.ema.europa.eu/en/ich-s2-r1-genotoxicity-testing-data-interpretation-pharmaceuticals-intended-human-use>
- EMA, CHMP, ICH S5 (R3) guideline on reproductive toxicology: Detection of toxicity to reproduction for human pharmaceuticals - step 5, EMA/CHMP/ICH/544278/1998, 18 February 2020, <https://www.ema.europa.eu/en/ich-s5-r3-guideline-reproductive-toxicology-detection-toxicity-reproduction-human-pharmaceuticals>
- EMA, CHMP, ICH guideline S6 (R1) on Preclinical safety evaluation of biotechnology-derived pharmaceuticals, CHMP/ICH/731268/1998, June 2011, <https://www.ema.europa.eu/en/ich-s6-r1-preclinical-safety-evaluation-biotechnology-derived-pharmaceuticals>
- EMA, CPMP, ICH guideline S7A on Safety pharmacology studies for human pharmaceuticals, CPMP/ICH/539/00, June 2001, <https://www.ema.europa.eu/en/ich-s7a-safety-pharmacology-studies-human-pharmaceuticals>
- EMA, CHMP, ICH guideline S8 Immunogenicity studies for human pharmaceuticals, CHMP/167235/2004, May 2006, <https://www.ema.europa.eu/en/ich-s8-immunotoxicity-studies-human-pharmaceuticals>

11. Clinical safety and efficacy

- Existing clinical guidance for the studied indication(s) should be consulted: <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety/clinical-efficacy-safety-general> and : <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-guidelines>

B. Reflection papers

1. Specific to ATMPs

- EMA, CAT, Reflection paper on classification of ATMPs Rev. 1, EMA/CAT/600280/2010 Rev. 1, 21 May 2015, https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-classification-advanced-therapy-medicinal-products_en-0.pdf <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification>

2. On medicinal products

- EMA, CHMP, Reflection paper providing an overview of the current regulatory testing requirements for medicinal products for human use and opportunities for implementation of the 3Rs, EMA/CHMP/CVMP/3Rs/742466/2015, 18 October 2018, <https://www.ema.europa.eu/en/overview-current-regulatory-testing-requirements-medicinal-products-human-use-opportunities>

C. Questions and answers

- EMA, CAT, Questions and answers on comparability considerations for advanced therapy medicinal products (ATMP), EMA/CAT/499821/2019, 6 December 2019, <https://www.ema.europa.eu/en/questions-answers-comparability-considerations-advanced-therapy-medicinal-products-atmp-scientific>
- EMA, Question and Answer on Good Laboratory Practice (GLP) principles in relation to ATMPs, 26 January 2017: https://www.ema.europa.eu/en/documents/other/good-laboratory-practice-glp-principles-relation-advanced-therapy-medicinal-products-atmps_en.pdf <https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/support-advanced-therapy-developers#glp-requirements-section>
- EMA, Inspections, Human Medicines, Pharmacovigilance and Committees Division, Questions and answers on the exemption from batch controls carried out on ATMPs imported into the European Union from a third country, EMA/354272/2019, 19 July 2019, https://www.ema.europa.eu/en/documents/other/questions-answers-exemption-batch-controls-carried-out-atmps-imported-european-union-third-country_en.pdf <https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/support-advanced-therapy-developers#gmp-requirements-section>

- EMA, CAT, Questions and answers on the use of out-of-specification batches of authorised cell/tissue-based advanced therapy medicinal products, EMA/CAT/224381/2019, 24 April 2019, https://www.ema.europa.eu/en/documents/other/questions-answers-use-out-specification-batches-authorised-cell-tissue-based-advanced-therapy_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/support-advanced-therapy-developers#gmp-requirements-section>
- EMA, Inspections, Human Medicines, Pharmacovigilance and Committees Division, Questions and answers on the principles of GMP for the manufacturing of starting materials of biological origin used to transfer genetic material for the manufacturing of ATMPs, EMA/246400/2021, 24 February 2021, https://www.ema.europa.eu/en/documents/other/questions-answers-principles-gmp-manufacturing-starting-materials-biological-origin-used-transfer_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/advanced-therapies/support-advanced-therapy-developers#gmp-requirements-section>

D. Position statements/papers

1. Position statements/papers specific to ATMPs

- EMA, CHMP, CAT, Creutzfeldt-Jakob disease and advanced therapy medicinal products, EMA/CHMP/BWP/353632/2010, 23 June 2011, <https://www.ema.europa.eu/en/creutzfeldt-jakob-disease-advanced-therapy-medicinal-products>

2. Position statements/papers on medicinal products

- EMA, Veterinary Medicines and Product Data Management, Statement of the EMA position on the application of the 3Rs (replacement, reduction and refinement) in the regulatory testing of human and veterinary medicinal products, EMA/470807/2011, 23 September 2011, https://www.ema.europa.eu/en/documents/other/statement-european-medicines-agency-position-application-3rs-replacement-reduction-refinement_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/ethical-use-animals-medicine-testing#ema-role-section>

3. Position statements/papers on Biologicals: drug product

- EMA, CPMP, CVMP, Position Paper on Re-establishment of working seeds and working cell banks using TSE compliant materials, EMEA/22314/02, 10 September 2002, <https://www.ema.europa.eu/en/re-establishment-working-seeds-working-cell-banks-using-tse-compliant-materials>

4. Position statements/papers on biologicals: drug substance

- EMA, CPMP, Position statement on the use of tumorigenic cells of human origin for the production of biological and biotechnological medicinal products,

CPMP/BWP/1143/00, 1 March 2001, <https://www.ema.europa.eu/en/use-tumorigenic-cells-human-origin-production-biological-biotechnological-medicinal-products>

E. Notes for guidance

1. Notes for guidance specific to ATMPs
 2. Notes for guidance on Biologicals: drug product
- EMA, Note for guidance on Development pharmaceuticals for biotechnological and biological products, CPMP/BWP/328/99, 21 October 1999, <https://www.ema.europa.eu/en/development-pharmaceutics-biotechnological-biological-products-annex-note-guidance-development>
 - EMA, CPMP, Note for guidance on development pharmaceuticals, CPMP/QWP/155/96, 28 January 1998, <https://www.ema.europa.eu/en/development-pharmaceutics-scientific-guideline>
 - EMA, Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products, EMA/410/01 Rev. 3, 5 March 2011, <https://www.ema.europa.eu/en/minimising-risk-transmitting-animal-spongiform-encephalopathy-agents-human-veterinary-medicinal>

F. Procedural advices

1. Specific to ATMPs
- EMA, CAT, Procedural advice on the provision of scientific recommendation on classification of ATMPs in accordance with Article 17 of Regulation (EC) No 1394/2007 (under revision - November 2020), EMA/CAT/99623/2009 Rev. 2, 5 November 2021, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-provision-scientific-recommendation-classification-advanced-therapy-medicinal/2007_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification>
 - EMA, Procedural advice on the evaluation of ATMPs, EMA/630043/2008, 25 January 2018, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-evaluation-advanced-therapy-medicinal-product-accordance-article-8-regulation-ec/2007_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/marketing-authorisation-procedures-advanced-therapy-medicinal-products#procedural-advice-on-the-evaluation-of-atmps-section>
 - EMA, CAT, Procedural advice on the evaluation of combined advanced therapy medicinal products and the consultation of Notified Bodies in accordance with Article 9 of Regulation (EC) No. 1394/2007, EMA/354785/2010, 11 February 2011, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-evaluation-combined-advanced-therapy-medicinal-products-consultation-notified/2007_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/marketing-authorisation-procedures-advanced-therapy-medicinal->

[products#procedural-advice-on-the-consultation-of-notified-bodies-in-the-case-of-a-combined-atmps-section](#)

2. For medicinal products

- EMA, CHMP, Procedural advice on the re-examination of CHMP opinions, EMEA/CHMP/50745/2005 Rev.1, 12 February 2009, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/procedural-advice-re-examination-chmp-opinions_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/marketing-authorisation-procedures-advanced-therapy-medicinal-products#procedural-advice-on-the-re-examination-of-committee-for-medicinal-products-for-human-use-opinion-section>

G. Other

1. Specific to ATMPs

- EMA, Inspections, Human Medicines, Pharmacovigilance and Committees Division, Development of non-substantially manipulated cell-based ATMPs : flexibility introduced via the application of the risk-based approach, EMA/CAT/216556/2017, 3 July 2017, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/development-non-substantially-manipulated-cell-based-advanced-therapy-medicinal-products-flexibility_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/marketing-authorisation-procedures-advanced-therapy-medicinal-products#guideline-on-the-risk-based-approach-according-to-annex-i,-part-iv-of-directive/2001/83/ec-applied-to-advanced-therapy-medicinal-products-section>
- EMA, CAT, EMA warns against using unproven cell-based therapies, 28 April 2020, EMA/CAT/94295/2020, https://www.ema.europa.eu/en/documents/public-statement/ema-warns-against-using-unproven-cell-based-therapies_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview>
- European Commission DG Health and Food Safety and European Medicines Agency, Action Plan on ATMPs, 20 October 2017, https://www.ema.europa.eu/en/documents/other/european-commission-dg-health-food-safety-european-medicines-agency-action-plan-advanced-therapy_en-0.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#action-plan-on-atmps-section>
- EMA, Guide on Advanced Therapy Medicinal Products - Quality flowchart, 29 November 2021, https://www.ema.europa.eu/en/documents/other/guide-advanced-therapy-medicinal-products-quality-flowchart_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#guidance-on-atmp-development-section>
- EMA, Guide on Advanced Therapy Medicinal Products- Quality checklist, 29 November 2021, https://www.ema.europa.eu/en/documents/other/guide-advanced-therapy-medicinal-products-quality-checklist_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#guidance-on-atmp-development-section>

- EMA, Guide on Advanced Therapy Medicinal Products - Non-clinical development flowchart, 29 November 2021, https://www.ema.europa.eu/en/documents/other/guide-advanced-therapy-medicinal-products-non-clinical-development-flowchart_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#guidance-on-atmp-development-section>
- EMA, Guide on Advanced Therapy Medicinal Products - Non-clinical development checklist, 29 November 2021, https://www.ema.europa.eu/en/documents/other/guide-advanced-therapy-medicinal-products-non-clinical-development-checklist_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#guidance-on-atmp-development-section>
- EMA, Guide on Advanced Therapy Medicinal Products - Clinical Development flowchart, 29 November 2021, https://www.ema.europa.eu/en/documents/other/guide-advanced-therapy-medicinal-products-clinical-development-flowchart_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#guidance-on-atmp-development-section>
- EMA, Guide on Advanced Therapy Medicinal Products - Clinical Development checklist, 29 November 2021, https://www.ema.europa.eu/en/documents/other/guide-advanced-therapy-medicinal-products-clinical-development-checklist_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/overview/advanced-therapy-medicinal-products-overview#guidance-on-atmp-development-section>
- EMA, CAT Scientific recommendations on classification of advanced therapy medicinal products, (updated on a quarterly basis), <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification/scientific-recommendations-classification-advanced-therapy-medicinal-products>

2. For medicinal products

- EMA, Administration and Corporate Management Division, Dossier requirements for centrally authorised products (CAPs), EMA/497021/2012 Rev. 26, 4 January 2021, <https://www.ema.europa.eu/en/news/simplification-submission-applications-centrally-authorized-medicines>
- EMA, CHMP, CVMP, Recommendation to marketing authorisation holders, highlighting the need to ensure compliance with 3Rs methods described in the European Pharmacopoeia, EMA/CHMP/CVMP/JEG-3Rs/252137/2012, 12 July 2012, https://www.ema.europa.eu/en/documents/scientific-guideline/recommendation-marketing-authorisation-holders-highlighting-need-ensure-compliance-3rs-methods_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/ethical-use-animals-medicine-testing#recommendations-on-3rs-in-european-pharmacopoeia-section>
- EMA, Heads of Medicines Agency, (EU innovation Network), Genome editing, EU-IN Horizon Scanning Report, EMA/319248/2020, 15 February 2021, https://www.ema.europa.eu/en/documents/report/genome-editing-eu-horizon-scanning-report_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#eu-innovation-network-section>
- EMA, Decision of the Executive Director on fee reductions for scientific advice requests on PRIME products for SMEs and applicants from the academic sector, EMA/63484/2016, 27 May 2016,

https://www.ema.europa.eu/en/documents/other/decision-executive-director-fee-reductions-scientific-advice-requests-prime-products-smes-applicants_en.pdf

<https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency#incentives-section>

- EMA, CHMP, Enhanced early dialogue to facilitate accelerated assessment of PRiority Medicines (PRIME), EMA/CHMP/57760/2015, Rev. 1, 7 May 2018, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/enhanced-early-dialogue-facilitate-accelerated-assessment-priority-medicines-prime_en.pdf
<https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines#background-information-section>
- EMA, Human Medicines Research and Development Support Division, Meeting report: Workshop with stakeholders on support to quality development in early access approaches, such as PRIME and Breakthrough Therapies, 26 November 2018, European Medicines Agency, London, EMA/CHMP/BWP/812924/2018, 25 July 2019, <https://www.ema.europa.eu/en/events/stakeholder-workshop-support-quality-development-early-access-approaches-such-prime-breakthrough>

III. Guidelines applicable to Gene Therapy Medicinal Products

A. Guidelines

1. Guidelines specific to Gene Therapy Medicinal Products

- EMA, CAT, Quality, preclinical and clinical aspects of gene therapy medicinal products, EMA/CAT/80183/2014, 22 March 2018, <https://www.ema.europa.eu/en/quality-preclinical-clinical-aspects-gene-therapy-medicinal-products>
- EMA, CAT, Quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells, EMA/CAT/GTWP/671639/2008 Rev. 1 – corr, 12 November 2020, <https://www.ema.europa.eu/en/quality-non-clinical-clinical-aspects-medicinal-products-containing-genetically-modified-cells>
- EMA, CHMP, Potency testing of cell-based immunotherapy medicinal products for the treatment of cancer, EMA/CHMP/BWP/271475/2006 rev.1, 21 July 2016, <https://www.ema.europa.eu/en/potency-testing-cell-based-immunotherapy-medicinal-products-treatment-cancer-0>
- EMA, CHMP, Development and manufacture of lentiviral vectors, CHMP/BWP/2458/03, 26 May 2005, <https://www.ema.europa.eu/en/development-manufacture-lentiviral-vectors>
- EMA, CHMP, Non-clinical studies required before first clinical use of gene therapy medicinal products, EMEA/CHMP/GTWP/125459/2006, 30 May 2008, <https://www.ema.europa.eu/en/non-clinical-studies-required-first-clinical-use-gene-therapy-medicinal-products>
- EMA, CHMP, Non-clinical testing for inadvertent germline transmission of gene transfer vectors, EMEA/273974/2005, 16 November 2006, <https://www.ema.europa.eu/en/non-clinical-testing-inadvertent-germline-transmission-gene-transfer-vectors>
- EMA, CHMP, Follow-up of patients administered with gene therapy medicinal products, EMEA/CHMP/GTWP/60436/2007, 22 October 2009, <https://www.ema.europa.eu/en/follow-patients-administered-gene-therapy-medicinal-products>

- EMA, CHMP, Guideline on scientific requirements for the environmental risk assessment of gene-therapy medicinal products, CHMP/GTWP/125491/06, 30 May 2008, <https://www.ema.europa.eu/en/scientific-requirements-environmental-risk-assessment-gene-therapy-medicinal-products>
- EMA, CHMP, Guideline on quality, non-clinical and clinical aspects of live recombinant viral vectored vaccines, EMA/CHMP/VWP/141697/2009, 24 June 2010, <https://www.ema.europa.eu/en/quality-non-clinical-clinical-aspects-live-recombinant-viral-vectored-vaccines>

2. Guidelines on Biologicals: drug substance

- EMA, CHMP, Guideline on development and manufacture of lentiviral vectors, CHMP/BWP/2458/03, 26 May 2005, <https://www.ema.europa.eu/en/development-manufacture-lentiviral-vectors>

3. ICH Guidelines on quality

- EMA, CPMP, ICH Q5B Analysis of the expression construct in cell lines used for production of r-DNA derived protein products, CPMP/ICH/139/95, July 1996, <https://www.ema.europa.eu/en/ich-q5b-analysis-expression-construct-cell-lines-used-production-rdna-derived-protein-products>

4. ICH Guidelines on non- clinical biodistribution

- EMA, CHMP, ICH S12 Guideline on nonclinical biodistribution considerations for gene therapy products – Step 5, EMA/CHMP/ICH/318372/2021, 19 April 2023, <https://www.ema.europa.eu/en/ich-guideline-s12-nonclinical-biodistribution-considerations-gene-therapy-products-step-2b>

5. ICH Considerations

- EMA, CHMP, General principles to address the risk of inadvertent germline integration of gene therapy vectors, CHMP/ICH/469991/2006, November 2006, <https://www.ema.europa.eu/en/ich-considerations-general-principles-address-risk-inadvertent-germline-integration-gene-therapy>
- EMA, CHMP, ICH Considerations: general principles to address virus and vector shedding, EMEA/CHMP/ICH/449035/2009, July 2009, <https://www.ema.europa.eu/en/ich-considerations-general-principles-address-virus-vector-shedding>
- EMA, CHMP, ICH Considerations: oncolytic viruses, EMEA/CHMP/ICH/607698/2008, October 2009, <https://www.ema.europa.eu/en/ich-considerations-oncolytic-viruses>

B. Reflection papers

- EMA, CAT, Design modifications of gene therapy medicinal products during development, EMA/CAT/GTWP/44236/2009, 14 December 2011,

<https://www.ema.europa.eu/en/design-modifications-gene-therapy-medicinal-products-during-development>

- EMA, CHMP, Quality, non-clinical and clinical issues relating specifically to recombinant adeno-associated viral vectors, CHMP/GTWP/587488/2007 Rev.1, 24 June 2010, <https://www.ema.europa.eu/en/quality-non-clinical-clinical-issues-relating-specifically-recombinant-adeno-associated-viral>
- EMA, CAT, Management of clinical risks deriving from insertional mutagenesis, EMA/CAT/190186/2012, 19 April 2013, <https://www.ema.europa.eu/en/management-clinical-risks-deriving-insertional-mutagenesis>

C. Questions and answers

- EMA, CHMP, Questions and answers on gene therapy, EMA/CAT/80183/2014, 17 December 2009, <https://www.ema.europa.eu/en/questions-answers-gene-therapy>

D. Notes for guidance

1. Notes for guidance specific to gene therapy medicinal products
 2. Notes for guidance on Biologicals : drug product
- EMA, CPMP, Note for guidance on virus validation studies: The design, contribution and interpretation of studies validating the inactivation and removal of viruses, CPMP/BWP/268/95 or 3AB8A, 14 February 1996, <https://www.ema.europa.eu/en/virus-validation-studies-design-contribution-interpretation-studies-validating-inactivation-removal>

E. European Pharmacopeia

- Ph.Eur chapter 2.6.16. Tests for extraneous agents in viral vaccines for human use (01/2011:20616), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20616
- Ph.Eur. General chapter 5.1.7 on viral safety (01/2008:50107), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/50107
- Ph.Eur. General chapter 5.2.3 on Cell substrates for the production of vaccines for human use (01/2017:50203), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/50203
- Ph.Eur. General chapter 5.2.12. Raw materials of biological origin for the production of cell based and gene therapy medicinal products (01/2017:50212), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/50212
- Ph.Eur. General chapter 5.14 on Gene transfer medicinal products for human use (01/2010:51400), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/51400
- Ph.Eur. General chapter 5.15. Functionality-related characteristics of excipients (07/2017:51500), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/51500

IV. Guidelines applicable to Cell Therapy and Tissue Engineering Medicinal Products

A. Guidelines

- CPMP, Gene Therapy Product Quality Aspects in the Production of Vectors and Genetically Modified Somatic Cells, 3AB6a, December 1994, <https://www.ema.europa.eu/en/gene-therapy-product-quality-aspects-production-vectors-genetically-modified-somatic-cells>
- EMA, CAT, Quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells, EMA/CAT/GTWP/671639/2008 Rev. 1 – Corr, 12 November 2020, <https://www.ema.europa.eu/en/quality-non-clinical-clinical-aspects-medicinal-products-containing-genetically-modified-cells>
- EMA, CHMP, Human cell-based medicinal products, EMEA/CHMP/410869/2006, 21 May 2008, <https://www.ema.europa.eu/en/human-cell-based-medicinal-products>
- EMA, CHMP, Guideline on Potency testing of cell-based immunotherapy medicinal products for the treatment of cancer, EMA/CHMP/BWP/271475/2006 rev.1, 21 July 2016, <https://www.ema.europa.eu/en/potency-testing-cell-based-immunotherapy-medicinal-products-treatment-cancer-0>
- EMA, CHMP, Xenogeneic cell-based medicinal products, EMEA/CHMP/CPWP/83508/2009, 22 October 2009, <https://www.ema.europa.eu/en/xenogeneic-cell-based-medicinal-products>

B. Reflection papers

- EMA, CAT, Clinical aspects related to tissue engineered products, EMA/CAT/573420/2009, 19 September 2014, <https://www.ema.europa.eu/en/clinical-aspects-related-tissue-engineered-products>
- EMA, CAT, In-vitro cultured chondrocyte containing products for cartilage repair of the knee, EMA/CAT/CPWP/568181/2009, 8 April 2010, <https://www.ema.europa.eu/en/vitro-cultured-chondrocyte-containing-products-cartilage-repair-knee>
- EMA, CAT, Stem cell-based medicinal products, EMA/CAT/571134/2009, 14 January 2011, <https://www.ema.europa.eu/en/stem-cell-based-medicinal-products>

C. Questions and answers

D. Position statements

E. Points to consider

- EMA, CPMP, Points to consider concerning endpoints in clinical studies with haematopoietic growth factors for mobilisation of autologous stem cells, CPMP/EWP/197/99, 17 February 2000, <https://www.ema.europa.eu/en/endpoints-clinical-studies-haematopoietic-growth-factors-mobilisation-autologous-stem-cells>

F. Notes for guidance

G. European Pharmacopeia

- Ph.Eur. monograph on human haematopoietic stem cells (Cellulae stirpes haematopoieticae humanae) Version 7.2, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/2323
- Ph.Eur. monograph on Method of analysis (2.7.23.) Numeration of CD34/CD45+ cells in haematopoietic products. Version 7.2, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20723
- Ph.Eur. monograph on Method of analysis (2.7.28.) Colony-forming cell assay for human haematopoietic progenitor cells. Version 7.2, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20728
- Ph.Eur. monograph on Nucleated Cell Count and Viability (2.7.29.), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20729
- Ph.Eur. monograph on Nucleic Acid Amplification Techniques (2.6.21.), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20621
- Ph.Eur. monograph on Flow Cytometry (2.7.24.), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20724
- Ph.Eur: (2.6.27) Microbiological control of cellular products, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20627
- Ph.Eur: (2.6.1.) Sterility, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20601
- Ph.Eur: (5.1.6) Alternative methods for control of microbiological quality, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/50106
- Ph.Eur. monograph Mycoplasmas (2.6.7.), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20607
- Ph.Eur. monograph on Bacterial endotoxins (2.6.14.), https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/20614
- General chapter 5.2.12 Raw materials for the production of cell-based and gene therapy medicinal products, https://extranet.edqm.eu/4DLink1/4DCGI/Web_View/mono/50212

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Annex 2.c to Deliverable D.4.7

List of attended Conferences, Workshops and Seminars

02/2021- 01/2022

University of Edinburgh and University of Aix-Marseille project teams attended the following conferences, workshops and seminars from February 2021 to January 2022:

Conferences

- SCI:COM 2021 “Shaping the story of science and research in Europe”
- International Society for Stem Cell Research Annual Meeting
- King's BHF Centre for Research Excellence Annual Symposium
- 31st Annual Meeting of Network for European CNS Transplantation and Restoration and 16th International Symposium on Neural Transplantation and Repair
- Royal Society of Biology Connect 2021: “Bringing outreach and engagement into the future”
- British Society for Immunology Annual Congress
- Chaire UNESCO, Chaire Jean Monnet, Inserm, Toulouse, « Analyse des risques en santé : entre droit(s), science, éthique et attente sociétale, approches européenne et nationale », Link to publication : <http://publications.ut-capitole.fr/42480/> , 12 March 2021,
- Association Française de Droit de la Santé, Défiance et Santé, 27 May 2021
- Université de Lorraine, CEDH et Biodroit, 18 June 2021
- Universidad Internacional Menendez Pelayo (UIMP), Basis for redesigning a post-pandemic health system, 1st July 2021
- Eurobiomed, “Rencontres Médicaments de thérapie innovante », 14 September 2021
- Agence de la Biomédecine, Journées de l'Agence de la biomédecine, 7-8 October 2021: <https://www.journees-agence-biomedecine.fr/programme>
- Chaire UNESCO « Éthique, science et société » et Institut Maurice Hauriou, Colloque Révision de la loi relative à la bioéthique, 14-15 October 2021 :

Workshops

- Hosted by the ATMP PPIE Working Group (co-led by NHS England and NHS Improvement and Genetic Alliance UK):
 - ATMP Patient Facing Information Discovery Workshops
 - Histology Independent Therapies Workshops:
 - Exploring patient and public information needs
 - Resource co-production
- Hosted by Centre for Law, Medicine and Life Sciences, University of Cambridge, Orphan Drug Innovation: Needs and Priorities, 17 September 2021

Seminars

- Cell and Gene Therapy Catapult Seminars:
 - Patient and public perspectives on cell and gene therapies
 - Solid tumour treatment with ATMPs
 - Pluripotent Stem Cell-derived advanced therapies
 - Accelerating delivery of cellular therapy trials
 - Out of specification ATMPs
 - Moving from autologous to allogeneic
 - Know your cells
 - Building a robust scaling strategy for stem cell manufacture
- Cell and Gene Therapy Insights:
 - Automated cell expansion: Current technologies and trends
 - Overcoming challenges in analytical assays for cellular therapies
- ADVANCE Webinars:
 - Regulatory & Clinical Aspects of ATMPs
 - EMA and EATRIS, Navigating the Regulatory Requirements for ATMPs, 29 November 2021: <https://eatris.eu/events/ema-and-eatris-present-navigating-the-regulatory-requirements-for-atmps/>
- Public Dialogue on Genome Editing in Life Sciences Research (ORION presentation of findings)
- From CRISPR to COVID: Communicating science in an age of moral dilemmas, uncertain science, and polarized politics (University of Edinburgh)
- Gene therapies for rare diseases – how to make this a success story in Europe? (Alliance for Regenerative Medicine)
- Socialising the Genome: Genomics, Public Trust and Engagement (Public Policy Projects)
- RESTORE - Health by Advanced Therapies Gene Therapy 2.0, 29 September 2021: <https://www.restore-horizon.eu/gene-therapy-2-webinar/>
- Launch of the UKAT and Challenges in clinical trials in Advanced Therapies (UK Advanced Therapies Network)
- ATMP Roadmap launch (ABPI & AAC)
- Hosted by GRP Health in Europe:
 - The Future of EU Health Law and Policy (Health Economics, Policy and Law Special Issue), 14 April 2021, link to publication: <https://www.cambridge-org.lama.univ-amu.fr/core/journals/health-economics-policy-and-law/issue/39EFAF9B49AC3C13203740DBB289DA12>
 - Towards a Healthy European Semester through ‘Green and Inclusive Growth’? A Research Agenda, 28 April 2021: https://estream.lancaster.ac.uk/GetMP4.ashx?ppID=2&file=38941_5m~f0ABXjcsPc.mp4&source=8&bb=0&bt=0&po=0&pi=0&ds=1471.23&so=4&st=0&tf=0&cs=717DPRRigK~0LnJq~Uy26g1npQWv1yj0BF7eWC7DujvUCB0aBh1FJPVHX10WWdpSyX~qDOCGtJeh~18uFJncww
 - The use of EU soft law in the making of domestic eHealth policies: from Electronic Health Records to Covid-19 contact tracing applications, 5 May 2021: https://estream.lancaster.ac.uk/GetMP4.ashx?ppID=2&file=38940_5l~EpkZm8Sira.mp4&source=8&bb=0&bt=0&po=0&pi=0&ds=1756.29&so=4&st=0&tf=0&cs=Qdq18rsmy7TLpNi_6oCA3q8H6IT9nq9SEzPICdSUIcT35QtuT2noV8JrJoYQHszt_RN_KrcU4luFM7OvD548sg

- EU Health Solidarity in Times of Crisis: Explaining Public Preferences Towards EU risk Pooling for Medicines, 12 May 2021: https://estream.lancaster.ac.uk/GetMP4.ashx?ppID=2&file=39295_5p~JcufbaKBqU.mp4&source=8&bb=0&bt=0&po=0&pi=0&ds=1802.4&so=31&st=0&tf=0&cs=plrbGhpmnoHiKN688zXSKL_VJkf5GNFoLB_jq8RPSB6NWGBqZrHIL_PuTZND2Gt17OKdIZCRd8rdvYdAtOh99g
- What progress in achieving transparency in pharmaceutical regulation? 23 June 2021: https://estream.lancaster.ac.uk/GetMP4.ashx?ppID=2&file=40625_5e~WGhZrLrYiH.mp4&source=8&bb=0&bt=0&po=0&pi=0&ds=2801.92&so=4&st=0&tf=0&cs=rfM3HwtXN5sC95DHC10p6a59s8P1CAI6fqj7hCb4T70Ny35uOA55GgoeQ1WSoKoZWFDs09kX7TjEdB0ryebkMA
- Hosted by EUPHA (The European Public Health Association),
 - Unleashing the Power of Law to Promote Better Health for All, 20 May 2021
 - The Oslo Medicines initiative : a new social contract with pharma, 11 June 2021
- Hosted by Institut für Ethik und Geschichte der Medizin Göttingen, Is it justifiable to edit the human germline? The 2020 Geneva Statement, 1st June 2021
- Hosted by Gene & Cell Therapy Institute:
 - Données patients & Blockchain, 22 June 2021
 - La bio-informatique de qualité réglementaire au service du développement des Médicaments de thérapie innovante, 8 July 2021
- Hosted by Bayer Pharmaceuticals, Regenerative medicines: How cell gene therapies may defeat incurable diseases one day, 24 June 2021
- Hosted by Société Française de Thérapie Génique et Cellulaire, Thérapie génique pour la maladie de Wilson : des challenges scientifiques à la translation clinique, 1^{er} October 2021 : <https://www.youtube.com/channel/UCaXNMgvGLRq4O3Oj29H7dew>
- Hosted by Nile:
 - Thérapies géniques, 8-9 June 2021 : <https://www.nile-consulting.eu/portfolio-item/livre-dactes-pour-lacces-des-malades-aux-therapies-geniques/>
 - Table ronde n°1 : Renforcer la politique européenne en faveur des maladies rares, 20 October 2021 : <https://www.nile-consulting.eu/portfolio-item/colloque-europe-de-la-sante/>
 - Table ronde n°2 : Le déploiement en Europe du concept « One Health », 21 October 2021 : <https://www.nile-consulting.eu/portfolio-item/colloque-europe-de-la-sante/>
 - Table ronde n°3 : Europe de la Santé : bilan et perspectives pour 2022-2023, 22 October 2021 : <https://www.nile-consulting.eu/portfolio-item/colloque-europe-de-la-sante/>
- Hosted by EU Health Policy Platform:
 - EU Health Policy Platform Pitch webinar, 2021 Thematic Network semi-finalists, Wednesday 7 July 2021
 - Thematic network “Health as a fundamental value. Towards an equitable and inclusive pharmaceutical strategy for the EU”, EU Health Policy Platform Kick-off meeting, 2021 Thematic Networks, Friday 24 September 2021
 - “EU values and health digitalization: the inclusion of vulnerable groups”, European Union Health Policy Platform, 2021 Thematic Network on « Health as fundamental value: Towards an equitable and inclusive pharmaceutical strategy for the EU”, 22 November 2021

- “Regulatory possibilities to enhance cooperation among the EU’s governance structures and complementarity within the EU acquis”, European Union Health Policy Platform, 2021 Thematic Network on « Health as fundamental value: Towards an equitable and inclusive pharmaceutical strategy for the EU”, 10 January 2022.

02/2022 – 07/2023

University of Edinburgh and University of Aix-Marseille project teams attended the following conferences, workshops, and seminars from February 2022 to July 2023:

Conferences

- EAHL Conference 2022, Ghent, Belgium, 20-22 April 2022
- 16th World Congress of Bioethics (WCB), « Bioethics post Covid-19: Responsibility and transparency in a globalized and interconnected world » (including topics on new technologies), International Association of Bioethics (IAB) hosted by the IBMB, Basel, Switzerland, 20-22 July 2022.
- 2022 International Mammalian Synthetic Biology Biology Workshop (mSBW) Edinburgh, UK, 28-29 July 2022
- ESGCT 29th Annual Congress, European Society of Gene and Cell Therapy in collaboration with British Society for Gene and Cell Therapy Gene and Cell Therapy – Posters presentation, Edinburgh, Scotland, 11-14 October 2022
- 15th European Public Health Conference, European Public Health Conference Foundation Strengthening health systems: improving population health and being prepared for the unexpected, Berlin, Germany, 9-12 November 2022
- Biosimilar medicines: multistakeholder event, Brussels, Belgium, 13 December 2022
- 49th Annual Meeting of the European Society for Blood and Marrow Transplantation Key issues relating to HSCT and cellular therapy research, Paris, France, 23-26 April 2023
- The Next Frontiers in ATMP Development, DG-GT (Deutsche Gesellschaft für Gentherapie), Paul-Ehrlich-Institut Langen, Germany, 27-28 April 2023
- Cell & Gene Therapy Insights Commercializing cell and gene therapies: Navigating complex commercial readiness hurdles for a successful product launch, Online event, 9 May 2023
- Annual meeting of the International Society for Gene and Cell Therapy Celebrating the progress of Advanced Therapies and building the Future through translations, Paris, France, 31 May-3 June 2023
- ITEGOREC, Innovations technologiques et greffe d'organes : enjeux réglementaires, éthiques et culturels (organoïdes), Compiègne, France, 14 June 2023
- CIVIS Blended Intensive Programme, The science, ethics and governance of human genome editing, University of Tübingen, Germany, 27 July-31 July 2023
- École d'été 2023 de la Chaire UNESCO Éthique, Science et Société Approches éthiques et juridiques de la vérité en science, 6-7 July 2023, Toulouse, France

Workshops

- Regulatory Science for Advanced (Gene and Cell) Therapies short courses, University College London, London, UK 07-08 Nov 2022
- Meeting of the OUP Online Encyclopaedia of European Union Law: Evolving EU health law following the Covid-19 pandemic, Faculty of Law- Maynooth, Ireland, 23 June 2023

Seminars

- Webinar 2: Regulatory possibilities to enhance cooperation among the EU's governance structures and complementarity within the EU acquis, EUHPP-EAHL IG, Webex, 10 January 2022
- « L'accès aux médicaments est-il un droit ? », Chaire Santé de l'école de droit de SciencePo Paris, Zoom, 16 February 2022
- Webinar 3: Political and legal issues linked to financing the development of pharmaceuticals all along their life-cycle, EUHPP - EAHL IG, Webex, 3 Mars 2022
- « Politique du médicament en France et en Europe », Académie Nationale de Pharmacie, 9 Mars 2022
- Innovation for Good: a Global Technology Governance Perspective, Professor David Winickoff, OECD Organisation for Economic Co-operation and Development), Law and Technologies Webinar Series | Oxford Law Faculty, 1 June 2022
- OUP Online Encyclopaedia seminar, The City Law School, London, UK, 10 June 2022
- The new Regulation on Health Technology Assessment (HTA), European Commission Directorate, The City Law School, London, UK, 10 June 2022
- The new Regulation on Health Technology Assessment (HTA), European Commission, Directorate-General for Health and Food Safety, Brussels, Belgium, 22 June 2022
- European Infrastructure for Translational Medicine and European Medicines Agency European Commission Webinar on Support for Academic and Non-Profit ATMP Developers, 1st December 2022
- EU Health Governance Research Network Webinar EU Pharmaceutical Activity: Challenges arising from the Pharmaceutical Strategy and Beyond, 25 January 2023
- GT 3M (Maladies rares, Mutation, Méditerranée) Séminaire interdisciplinaire essais cliniques, Marseille, France, 13 April 2023
- Online event TESaCo (technologies émergentes et sagesse collective) Biotechnologies : quelle sagesse collective ?, CRISPR-Cas9 Genome Editing, 11 May 2023
- Online event TESaCo (technologies émergentes et sagesse collective) Biotechnologies : quelle sagesse collective ?, Novel forms of life: organoids, 22 May 2023
- Webinars hosted by Alliance for Regenerative Medicine (ARM) :
 - A-Gene Webinar Series - Alliance for Regenerative Medicine (on demand)
 - A-Cell Webinar Series - Alliance for Regenerative Medicine (on demand)
 - Future of ATMPs in Europe - Alliance for Regenerative Medicine, November 29 2022
- Webinar hosted by Cell and Gene Therapy Insights:
 - The CAR Toolkit: Progress and Challenges in CAR T/NK Cell R&D and manufacture, 07 Dec 2022
- EATRIS ADVANCE Webinars:

- European Innovation Council (EIC) and European Medicine Agency (EMA) Info Day, 31 Jan 2023
- ADVANCE Webinar: ATMP Market Access, 20 Dec 2022
- EATRIS and EMA Present: Webinar on Support for Academic and Non-Profit ATMP Developers, 01 Dec 2022
- ADVANCE Webinar - Manufacturing of ATMPs, 29 Nov 2022
- Training seminar in regulatory knowledge, 05 Oct 2022
- ADVANCE Webinar: Regulatory & Clinical Aspects of ATMPs, 31 May 2022
- Webinar hosted by NVIDIA:
 - The Impact of Large Language Models (LLM) on Life Sciences, 11 May 2023
- Webinar hosted by FierceBiotech:
 - Navigating the Current Launch Landscape Trends, 29 Jun 2023
- Webinars hosted by Bioanalysis Zone:
 - Best Practices for laboratory solutions relating to cell and gene therapy clinical trials, 7 Dec 2022
 - Validating flow cytometry assays for cell and gene therapies, 10 Nov 2022

Workshop Hosted

- EuroGCT Sharing best practice workshop, Edinburgh, UK, 10 Oct 2022
- Generative AI and Gene and Cell Therapy Information Workshop, hosted by University of Edinburgh, ReNEW and the University of Copenhagen, Copenhagen, Denmark, 17-18 Apr 2023

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Annex 2.d to Deliverable D.4.7

List of Social and Human Sciences databases

The following SHS databases should be consulted in order to establish a bibliography on ELSI aspects of gene and cell therapy.

1. Dalloz

2. HeinOnline

3. Lexbase

4. LexisNexis (dans revues)

5. Lextenso (dans revues)

6. Navis (dans revues)

7. Westlaw UK (Journals)

8. Brill revues - Archives ISTEEX

9. Cairn revues

10. Doctrinal Plus

11. Bibliothèque numérique en droit de la santé (BNDS)

12. Wiley Online Library

13. Lamyline Reflex

14. Cambridge University Press Revues - Archives ISTEK

15. De Gruyter revues - Archives ISTEK

16. Encyclopédie Max Planck de droit international public

17. JSTOR

18. Law Review Commons

19. OpenEdition Journals

20. ScienceDirect – SD

21. Springer Nature - ebooks et revues - Archives Istex

22. Web of Science

23. Google Scholar

24. PubMed

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Annex 3.a to Deliverable D.4.7

Template Research Record for bibliography

This template below should be copied and pasted for each research on scientific databases.

NAME of the Bibliography

Name of the researcher:

Date of the research:

Last updated:

Topic of the research:

For EACH below database:

a) Precise research method:

- *Exact key word(s) and research method (« » ; * ; AND ; OR...).*
- *Please be as precise as possible. This is all the more important than not all databases will support boolean research (for instance no * on Dalloz), or not all databases will offer the same advanced research options (some will offer to select a time frame from the beginning, others will only have it as a filter of results after; some will offer to specify that you want only the results where the keyword appears in, the title or abstract, some won't have this option and you may have to do it yourself...)*
- *Adapt the language (French or English) to the chosen database and be specific on how you translated the key words (for instance regenerative medicine: médecine régénérative/régénératrice?; think of using the *)*

b) Total number of results from the data base:

c) Further exclusion criteria:

Any further filter that you can add after (either in the search functions of the database, or a relevance criterion that you have in mind when going through all the results)

d) Final number of selected results:

These results should be added to the relevant shared library.

Phase I

1. Dalloz

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

2. HeinOnline

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

3. Lexbase

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

4. LexisNexis (dans revues)

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

5. Lextenso (dans revues)

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

6. Navis (dans revues)

- a) Research method
- b) Number of results
- c) Exclusion criteria

d) Final number of results included in Zotero

7. Westlaw UK (Journals)

a) Research method

b) Number of results

c) Exclusion criteria

d) Final number of results included in Zotero

8. Brill revues - Archives ISTEK

a) Research method

b) Number of results

c) Exclusion criteria

d) Final number of results included in Zotero

9. Cairn revues

a) Research method

b) Number of results

c) Exclusion criteria

d) Final number of results included in Zotero

10. Doctrinal Plus

a) Research method

b) Number of results

c) Exclusion criteria

d) Final number of results included in Zotero

Phase II

11. Bibliothèque numérique en droit de la santé (BNDS)

a) Research method

b) Number of results

c) Exclusion criteria

d) Final number of results included in Zotero

12. Wiley Online Library

a) Research method

- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

13. Lamyline Reflex

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

14. Cambridge University Press Revues - Archives ISTEK

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

15. De Gruyter revues - Archives ISTEK

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

16. Encyclopédie Max Planck de droit international public

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

17. JSTOR

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

18. Law Review Commons

- a) Research method

- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

19. OpenEdition Journals

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

20. ScienceDirect – SD

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

21. Springer Nature - ebooks et revues - Archives Istex

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

22. Web of Science

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

23. Google Scholar

- a) Research method
- b) Number of results
- c) Exclusion criteria
- d) Final number of results included in Zotero

24. PubMed

- a) Research method

b) Number of results

c) Exclusion criteria

d) Final number of results included in Zotero

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Annex 3.b to Deliverable D.4.7

Structure for creating lay summaries of Social and Human Sciences research papers

The relative word counts for each section are given as a guide and may change depending on the emphasis of the study. The key is to keep it short.

1. Title

A simple, clear title, which will usually involve changing the paper's title.

2. Summary (Maximum 120 words)

Gives a clear overview of the study and is stand-alone from the rest of the text (some may only read the summary). Include why the study was done, what was found and the implications. You could use bullet points.

3. What is the scope of the paper? (Maximum 120 words)

Which country/ies is/are covered? What is the scientific discipline of this paper (law, sociology, STS, interdisciplinary...)? What is the object covered this paper (advanced therapy, blood, CAR-T cells...)?

4. What are the key aspects of the paper? (Maximum 500 words)

Details the main ideas of the paper going a step further than what is said in **2**. You could use bullet points.

5. What is the layout of the paper?

Provides the table of contents of the paper, its titles and subtitles showing how the author has framed the paper.

6. Further information and links

Link to scientific abstract and the full article if available. Also include any relevant other material which could include papers and information sites.

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Annex 3.c to Deliverable D.4.7

Template for creating lay summaries of guidelines

The relative word counts for each section are given as a guide and may change depending on the emphasis of the guideline and whether its scope is basic, translational or clinical. The key is to keep it short.

1. Title

2. Summary (Maximum 120 words)

Gives a clear overview of the guideline and is stand-alone from the rest of the text (some may only read the summary). Include why the guideline was done, what was proposed and the implications. You could use bullet points.

3. What is the idea behind this guideline? (Maximum 150 words)

Why was this guideline done? Give any relevant background to the guideline, including previous guideline, guidelines from other parts of the world, guidelines on similar topics, and relate to any relevant conditions.

4. What is the scope of this guideline? (Maximum 150 words)

What is the field of application of this guideline (therapy, indication, pathology, legal classification of products)?

5. What are the key points of this guideline? (Maximum 200 words)

What are the main recommendations of this guideline?

6. What does this mean for researchers and companies? (Maximum 250 words)

This is the part that will be of most interest to readers. Be realistic, describing what the recommendations mean in relation to works' organisation and experimental studies.

7. What could be the consequences for patients? (Maximum 250 words)

What are the intended consequences for patients?' 'How could these guidelines protect/help/benefit patients?

8. Further information and links

Link to guidelines. Also include any relevant other material which could include papers and information sites relating to this guideline.

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Annex 3.d to Deliverable D.4.7

Follow-up table for requests of lay summaries and translations

Lay summary title	Original Author(s)	Original Title (if relevant)	Reviewer	Date 1st contact with the reviewer	Date of the reminder	Reviewed date	Approval date	Approval person	Status	Translation needed (major/minor/no changes)

FR - Responsible for translation	Date 1st contact with the translator	Date lay summary sent to the translator	Date of the reminder (if relevant)	FR - date translation completed

DE - Responsible	Date 1st contact with the translator	Date lay summary sent to the translator	Date of the reminder (if relevant)	DE - date translation completed

IT - Responsible	Date 1st contact with the translator	Date lay summary sent to the translator	Date of the reminder (if relevant)	IT - date translation completed

PL - Responsible	Date 1st contact with the translator	Date lay summary sent to the translator	Date of the reminder (if relevant)	PL - date translation completed

ES - Responsible	Date 1st contact with the translator	Date lay summary sent to the translator	Date of the reminder (if relevant)	ES - date translation completed

P- Responsible	Date 1st contact with the translator	Date lay summary sent to the translator	Date of the reminder (if relevant)	P - date translation completed

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Annex 4 to Deliverable D.4.7

List of Social and Human Sciences Research Centres active on Gene and Cell Therapy

These research centres are part of the relevant network of Partner 2 in order to gather information on ELSI aspects of gene and cell therapy for EuroGCT. This initial list is indicative and will be expanded throughout the project's duration.

Last update: 11 July 2023

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II. Austria

Management Center Innsbruck (MCI), The Entrepreneurial School®, Innsbruck, Germany:
<https://www.mci4me.at/de/>

III. Belgium

Bioethics Institute Ghent (BIG), Ghent University, Ghent, Belgium:
<https://www.bioethics.ugent.be/>

Ghent University, Ghent, Belgium: <https://www.ugent.be/en>

Ghent University, Faculty of Law and Criminology, Ghent, Belgium :
<https://www.ugent.be/re/en>

IV. Bulgaria

V. Croatia

Catholic University of Croatia, Zagreb, Croatia: <https://www.unicath.hr/eng/home>

VI. Republic of Cyprus

VII. Czech Republic

Masaryk University, Faculty of Law - Institute of Law and Technology, Brno, Czech Republic:
<https://www.muni.cz/en/about-us/organizational-structure/faculty-of-law/222200-institute-of-law-and-technology>

VIII. Denmark

JUR Centre for Advanced Studies in Biomedical Innovation Law: <https://jura.ku.dk/cebil/>

Centre for Legal Studies in Welfare and Market, University of Copenhagen, Denmark:
<https://jura.ku.dk/english/welma/>

IX. Estonia

X. Finland

University of Helsinki, Faculty of Law

University of Lapland, Welfare Law Research Group, Rovaniemi, Finland:
<https://www.ulapland.fi/FI/Kotisivut/Hyvinvointioikeuden-tutkimusryhma>

XI. France

Centre for the Sociology of Innovation, Paris, France:
<https://www.csi.minesparis.psl.eu/en/about-the-csi/>

European, International, and Comparative Laws DICE, CERIC- Aix-Marseille Université, Université de Toulon, Université Pau & Pays Adour, Aix-en-Provence, France, UMR7318 Droits international, comparé et européen, France

ADES (UMR 7268), bio-cultural anthropology, law, ethics and health, CDSA, Aix-Marseille Université, France : <https://ades.hypotheses.org/>

CERPOP, UMR 1295, Inserm, Université de Toulouse - Université Paul Sabatier -Toulouse III, Université Toulouse III Paul Sabatier, France

CEVIPOF, Paris

IRDEIC, Université Toulouse 1- Capitole

CREDIMI, Université de Bourgogne, Dijon, France

IRENEE, Université de Lorraine, Nancy, France : <https://irenee.univ-lorraine.fr/fr>

XII. Germany

Centre for Ethics and Law in the Life Sciences, University of Hannover: <https://www.cells.uni-hannover.de/en/>

Chair of Constitutional and Administrative Law, Public International Law, European and International Economic Law, University of Passau: <https://www.jura.uni-passau.de/en/dederer/>

Institute of Ethics and History of Medicine, University of Tübingen, Tübingen, Germany: <https://www.medizin.uni-tuebingen.de/de/das-klinikum/einrichtungen/institute/ethik-und-geschichte-der-medizin>

Martin-Luther-University Halle-Wittenberg, Germany

University of Bonn, Faculty of Law, Centre for Life Sciences and Law, Bonn, Germany: <https://www.jura.uni-bonn.de/en/centre-for-the-law-of-life-sciences>

XIII. Greece

Department of Political Science and History, Panteion University. School of Political Sciences, Athens, Greece: https://polhist.panteion.gr/index.php?option=com_content&view=featured&Itemid=681&lang=en

XIV. Hungary

Centre for Ethics and Law in Biomedicine: <https://www.ceu.edu/unit/celab>

University of Debrecen, Faculty of Public Health, Debrecen, Hungary

Central European University, Department of Legal Studies, Budapest, Hungary: <https://legal.ceu.edu/>

Central European University, Department of Gender Studies, Budapest, Hungary:
<https://people.ceu.edu/unit/gender>

Central European University, Department of Political Science, Budapest, Hungary:
<https://people.ceu.edu/unit/polsci>

Central European University, Doctoral School of Political Science, Public Policy, and
International Relations, Budapest, Hungary: <https://people.ceu.edu/unit/dsps>

XV. Ireland

Trinity College Dublin, School of Law, Dublin, Ireland: <https://www.tcd.ie/law/>

Dublin City University, School of Law and Government, Dublin, Ireland;
<https://www.dcu.ie/lawandgovernment/>

Centre of Bioethical Research and Analysis, National University of Ireland (Galway)

XVI. Italy

University Di Torino, Italy

European Center for Law, Science and new Technologies (ECLT), University of Pavia

University of Salerno, School of Law

European University Institute, Department of Law, San Domenico di Fiesole, Italy:
<https://www.eui.eu/en/academic-units/department-of-law>

XVII. Latvia

Rīga Stradiņš University, Riga, Latvia: <https://www.rsu.lv/en>

XVIII. Lithuania

Kaunas University of Technology, Lithuania

XIX. Luxembourg

Service national d'information et de médiation en santé, Luxembourg, Luxembourg :
<https://mediateursante.public.lu/fr.html>

XX. Malta

XXI. Netherlands

Faculty of Law, University of Amsterdam

Maastricht university

Centre for Medical Systems Biology, Faculty of Law, University of Leiden

XXII. Poland

University of Warsaw

XXIII. Portugal

University of Coimbra

Centre for Philosophy of Science of the University of Lisbon (CFCUL)

University of Lisbon

NOVA University Lisbon, School of Law, Lisbon, Portugal : <https://novalaw.unl.pt/en/>

XXIV. Romania

XXV. Slovakia

XXVI. Slovenia

XXVII. Spain

Chair in law and the human genome, Grupo de Investigación de la Universidad del País Vasco UPV/EHU: <https://bioderecho.eu/presentacion/>

IDIVAL-University of Cantabria

XXVIII. Sweden

Department of International Law and Human Rights Law, Lund University, Sweden

Medical Ethics, Lund University, Sweden

Faculty of Law, University of Uppsala

XXIX. Switzerland

Health Ethics and Policy Lab, Department of Health Sciences and Technology – ETH Zurich: <https://bioethics.ethz.ch/the-group.html>

Swiss Institute of Comparative Law

University of Basel, Faculty of Law, Center for Life Sciences Law (CLSL), Basel, Switzerland: <https://ius.unibas.ch/de/zlsr/>

XXX. United Kingdom

Centre for Ethics, Law and Society, Cardiff University: <http://www.ccels.cardiff.ac.uk/>

Centre for Health and Social Care Law, Cardiff University: <http://www.law.cf.ac.uk/chscl/>

Centre for Technology, Ethics & Law in Society (TELOS), King's College London: <http://www.kcl.ac.uk/law/research/centres/telos/index.aspx>

Center for Global Health Policy, School of Global Studies- University of Sussex: <http://www.sussex.ac.uk/globalhealthpolicy/>

Center of Health, Law, and Emerging Technologies (HeLex), Nuffield Department of Population Health, University of Oxford: <http://www.dph.ox.ac.uk/helex>

Centre for Health and Clinical Research- University of West England (Bristol): <http://www1.uwe.ac.uk/hls/research/clinicalandhealthresearch.aspx>

Centre for Social Ethics and Policy, University of Manchester:
<http://www.law.manchester.ac.uk/csep/about-csep/>

Centre for the Analysis of Risk and Regulation (CARR), London School of Economics and Political Science <http://www.lse.ac.uk/researchAndExpertise/units/CARR/home.aspx>

Centre for the study of incentives in health (CSI Health is a collaboration between King's College London, Queen Mary University of London & The London School of Economics and is funded by a Strategic Award in Biomedical Ethics from Wellcome Trust):
<http://www.kcl.ac.uk/ioppn/research/centres/csihealth/index.aspx>

Ethox Centre, Nuffield Department of Population Health, University of Oxford:
<http://www.ethox.ox.ac.uk/>

Global Biopolitics Research Centre- King's College London:
<http://www.kcl.ac.uk/sspp/departments/politicaeconomy/research/biopolitics/index.aspx>

Healthcare Law and Bioethics, School of Law, Keele University:
<http://www.keele.ac.uk/law/research/researchclusters/healthcarelawandbioethicshlb/>

Institute for Innovation Generation in the Life Sciences (Innogen): <http://www.innogen.ac.uk/>

Institute for Science, Ethics and Innovation, School of Law, University of Manchester:
<http://www.isei.manchester.ac.uk/>

Law Department, London School of Economics:
<http://www.lse.ac.uk/collections/law/index.htm>

Medical Technology Research Group (MRTG) at the London School of Economics (LSE):
<http://www.lse.ac.uk/LSEHealthAndSocialCare/research/LSEHealth/MTRG/home.aspx>

Science and Technology Studies Unit - University of York: <http://www.york.ac.uk/satsu/>

School of health and population sciences University of Birmingham:
<http://www.birmingham.ac.uk/schools/haps/index.aspx>

Centre for Health Law Science and Policy, Birmingham Law School, University of Birmingham, Birmingham, UK : <https://www.birmingham.ac.uk/research/chlsp/index.aspx>

Department of sociological studies, The University of Sheffield, United Kingdom:
<https://www.sheffield.ac.uk/socstudies>

Faculty of Law, Queen's University of Belfast

Centre for Biomedicine, Self and Society, University of Edinburgh:
<https://www.ed.ac.uk/usher/biomedicine-self-society>

City, University of London, The City Law School, London, UK:
<https://www.city.ac.uk/about/schools/law>

University of Sussex, School of Law, Politics and Sociology, Sussex, UK:
<http://www.sussex.ac.uk/lps/>

Liverpool John Moores University, Faculty of Business and Law, School of Law, Liverpool, UK: <https://www.ljmu.ac.uk/about-us/faculties/faculty-of-business-and-law/school-of-law>

Brunel University London, Brunel Law School, College of Business, Arts and Social Sciences,
Uxbridge, UK: <https://www.brunel.ac.uk/about/cbass>

XXXI. Australia

Centre for Law and Genetics, Law Faculty, University of Tasmania, Hobart, TAS, Australia

School of Social Sciences, University of Monash

Faculty of Medicine, University of Melbourne

XXXII. Canada

Johnson Shoyama Graduate School of Public Policy, University of Regina

Health Law Institute, University of Alberta