

EuroGCT D4-2: Resources on practical steps- a set of information resources on the practical steps needed for cell and gene therapy development

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Project acronym: EuroGCT

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

Deliverable: D4.2 Resources on practical steps

A set of information resources on the practical steps needed for cell and gene therapy development

Date: 31st July 2023



Project	
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D 4.2 – Resources on practical steps, a set of information resources on the practical steps needed for cell and gene therapy development

The European Consortium for Communicating Gene and Cell Therapy Information (EuroGCT) has two major objectives:

• To provide patients, people affected by conditions, healthcare professionals and citizens with accurate scientific, legal, ethical and societal information and with engagement opportunities, and thus to support better informed decision-making related to cell and gene-based therapies.

• To facilitate better decision-making at key points in development of new therapies and thus enable improved product development, by providing the research community and regulatory and healthcare authorities with an information source on the practical steps needed for cell and gene therapy development.

Work Package 4 (WP4) is developing an information hub for the research and regulatory communities that facilitates access of these communities to information on the practical steps needed for cell- and gene-based therapy development and promotes information exchange within and between these communities.

Deliverable 4.2 is a set of information resources on the practical steps needed for cell and gene therapy development, which can be viewed online at <u>www.eurogct.org/research-pathways</u>.



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Screenshot of Research Pathways information hub: www.eurogct.org/research-pathways 12:26, 26 July 2023



The Research Pathways page has been redeveloped and published online as a filterable and searchable database. (Details in **D4.1**). The indexed database contains information on practical steps needed for cell and gene therapy development developed by the EuroGCT consortium or signposting to external resources. These resources include guidance on manufacturing guidelines, regulatory and scientific guidelines, intellectual property rights, market acceptability and ethical matters. It builds on the initial information published (**D4.9**), and further enhanced by the new search/filter functions, links to grouped topical sections, as well as new content developed by the project and signposting to additional collated resources. Contents within Research Pathways will be continuously updated throughout the project duration.

The Research Pathways page also offers a gateway towards topical sections outlined as follows:

- **Key Research Pathways**: this section contains the collection of resources developed by EuroGCT WP4.
- Key Pathway Resources: this section contains collated key resources on ATMP development by medicines agencies, and existing complementary work produced by other organisations.
- **Case Studies**: this section contains our collection of new 'case study' content type, presenting collated resources on the development of specific ATMPs.
- **Patient and Public Involvement**: this links to the ATMP Engage Patient and Public Involvement (PPI) Directory, a searchable and filterable directory with PPI resources for developers of cell and gene therapies.
- **Actors and Network**: this section contains our initial mapping of stakeholders in ATMP development, covering the breadth of advanced therapies activities in Europe and beyond.

Screenshots of these sections along with example pages will be shown in the following pages of this report.



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Screenshot of Key Research Pathways: <u>www.eurogct.org/research-pathways/key-research-pathways</u> 12:26, 26 July, 2023

The 'Key Research Pathways' section contains the collection of original resources produced by the EuroGCT WP4. These guides are categorised into six main groups: Research and Innovation, Therapy Classification, Manufacturing, Commercialisation, Actors and Networks, and Public Involvement and Data. Each category has short introduction text and links to published EuroGCT guides for the practical steps available at each stage of development.



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Screenshot of 'Conditional Marketing Authorisation' entry: <u>www.eurogct.org/research-pathways/commercialisation/market-access-atmps/expediting-marketing-authorisation-0</u> 12:41, 27 June, 2023

This is an example page of EuroGCT's original resource. More published resources can be directly accessed through the Key Research Pathways Section: <u>www.eurogct.org/research-pathways/key-research-pathways</u> or be found through searching in the main Research Pathways database: <u>https://www.eurogct.org/research-pathways</u>



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Screenshot of 'Key Pathway Resources': <u>www.eurogct.org/key-pathway-resources</u> 12:41, 27 June, 2023

The 'Key Pathway Resources' section contains a collection of key resources on ATMP development published by European Medicines Agency (EMA), other projects, and/or organisations active in the field of gene and cell therapy.





Home / Case Studies

Case Studies

This section contains case studies on ATMP development. Follow the links below to learn about the development processes, the keys to success, the challenges and how developers overcame them:

Case study: Holoclar	Case Study: Strimvelis	
learn about the development of Holoclar Go to case study	A successful public-private partnership bringing ATMP to market Go to case study	
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Screenshot of 'Case study' section: www.eurogct.org/case-studies 12:41, 26 July, 2023

The 'Case Studies' section contains case studies on ATMP development. Currently there are two case studies on approved ATMPs (Holoclar and Strimvelis). Future work will involve codeveloping case studies with partners for them to share their experiences and learnings in ATMP development. More details can be found in **D4.1**- Landscape mapping.

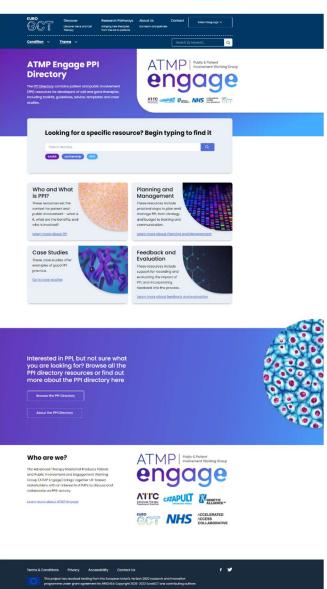


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Screenshot of 'Case Study: Holoclar': www.eurogct.org/case-study-holoclar 12:41, 27 June, 2023

Here is an example of case study pages. In this case study for Holoclar, we collated existing information about each stage of its development, from early-stage research to approval and beyond, to serve as a guide for the research community to learn about the development process, the keys to success, the challenges and how developers overcame them. These case studies provide researchers and developers with an opportunity to engage with and to create supporting resources for the researcher and developer community.

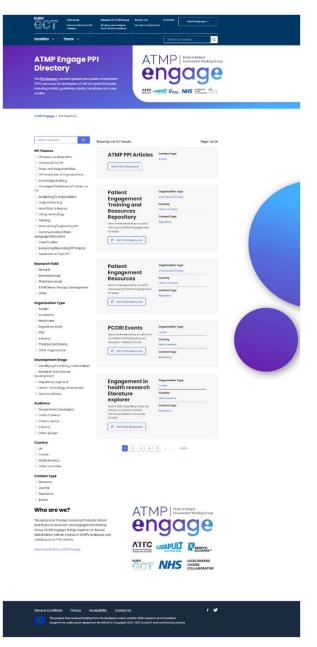




Screenshot of 'Patient and Public Involvement (landing page)': www.eurogct.org/ppi-directory 13:05, 27 June, 2023

The 'Patient and Public Involvement' (PPI) section is linked to the ATMP Engage PPI Directory. This directory contains more than 150 PPI resources for developers of cell and gene therapies, including toolkits, guidelines, advice, templates and case studies.





Screenshot of 'Patient and Public Involvement (search page)': <u>www.eurogct.org/atmp-ppi-database</u> 13:05, 27 June, 2023

The collated PPI resources in this directory are fully indexed, making it searchable and filterable.



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Screenshot of 'Actors and Network': <u>www.eurogct.org/research-pathways/actors-and-networks</u> 13:05, 26 July, 2023

The 'Actors and Network' section contains our initial information on the mapping of gene and cell therapy stakeholders in Europe and beyond. It will be further developed and reported in **D4.3** due month 48.