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## **EuroGCT Deliverable D4.3: Searchable map, Report on development of a searchable map of cell and gene-based therapy activity in Europe**

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## ***Deliverable Report***

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

***Deliverable: D.4.3 Searchable Map***

***Report on development of a searchable map of cell and gene-based  
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## List of acronyms

**ATMP:** Advanced Therapy Medicinal Products

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

**ESGCT:** European Society of Gene and Cell Therapy

**GCT:** Gene and Cell Therapy

**IMHT:** The EuroGCT Information Management Hub Team, comprised of project staff employed directly by the project, based at the University of Edinburgh (UEDIN) and Aix-Marseille University (AMU)

**WP:** Work Package

**HTA:** Health Technology Assessment

## **D4.3 Searchable map, Report on development of a searchable map of cell and gene-based therapy activity in Europe**

### **1. Summary**

**WP4**, entitled “An Information and Engagement Hub for the Research and Regulatory Communities”, is focussed on development of 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 4.3** reports on further developments regarding task 4 of WP4: “Develop a map of European activity related to cell and gene therapy development including the academic, clinical and industrial landscapes, health economists, and government agencies”. It focusses on building a multi-layered searchable map of the cell and gene-based therapy landscape in Europe, mounted on [www.eurogct.org](http://www.eurogct.org), and openly accessible. This deliverable provides an update to the earlier deliverable, **D.4.8 Initial Landscape Mapping** submitted in the first reporting period. **D4.8** reported the mapping, performed by EuroGCT, of the European landscapes associated with gene and cell therapy related product development pathways including ethical, legal, regulatory and societal issues (ELSI). Related, **D4.7 Information collation**, submitted in the first reporting period, and re-submitted in the second reporting period, detailed our methodology for information collection and curation. The present report, **D4.3**, therefore, moves beyond the mapping of practical steps for GCT development to focus on “who” is actively contributing to the GCT field in Europe through various ways, and to show our framework for information expansion in this actively growing field.

The evolving field of gene and cell therapy is supported by a large and growing community of academic, clinical, translational, corporate, regulatory, and patient organisations. The EuroGCT “Actors and Networks” database maps these stakeholders in Europe and beyond, and where possible and available, their activities, and resources they have produced. Based on EuroGCT’s mapping activity, our findings are being compiled, and this database has been developed for those interested in identifying the actors involved at each stage of the pathways bringing gene and cell therapies from lab to clinic. Our focus is to map information that has not been mapped elsewhere, but we also signpost to existing actors mapping where it exists. This includes documenting the various types of regulators, patient groups actively involved along the pathways, and non-profit organisations devoted to therapy development.

The information on actors in the thriving field of GCT is vast and evolving rapidly. In the first iteration of this database, it does not yet include commercial partners and service providers. At the time of reporting, a set of identified actors has been entered into this database, while ongoing effort has been on promoting this database through distributing an online questionnaire for actors to fill in for determining how their information is represented in this database.

The outputs are published on the EuroGCT website in the Research Pathways section (<https://www.eurogct.org/research-pathways/actors-and-networks-database>) as a searchable and filterable database and will continually be updated and expanded throughout the course of the project.

## 2. The Actors and Networks Map

This deliverable is built on the initial work reported in **D4.8** and further updated and populated with new information collated based on methodology listed in **D4.7**.

In this section, we report on how the scope of actors was determined for the Actors and Networks map and how we organised our actors' inventory.

### 2.1. Scope of Actors

The first step towards building the European GCT stakeholder map was to determine the scope of the map.

We started from consulting existing work on such mapping. The most established existing map is the European Gene and Cell Therapy (ESGCT) heatmap. It presents the GCT actors involved in academic research, clinical sites as well as private companies through seven main criteria: country of headquarter, type of organisation, lab/company with weblink, Institute, Field of Medicine, Lab techniques, and More information on an interactive interface.

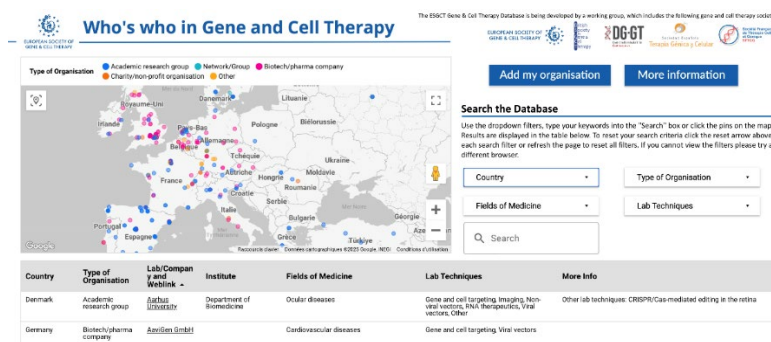


Figure 1. Screenshot of the ESGCT Who's Who Database. (see: <https://www.esgct.eu/heatmap>)

After consulting existing work on GCT stakeholders' mapping<sup>1234567</sup>, we identified two major missing gaps in these proposed-built maps:

- The first missing gap identified was the various types of regulators playing a vital role in all stages of GCT development. The term “regulators” here has a wide meaning--it covers all regulatory agencies involved in gene and cell therapies, especially regarding the advanced therapy medicinal products' development pathway. Regulators in the wide meaning is any competent authorities, including but not limited to those from Medicines Agencies, National competent authorities, HTA Bodies, Ethics Committees, Data Authorities, Patent Offices, Research Funding Authorities. To navigate the landscape of regulatory authorities in GCT development is crucial for any developer, but how to do so and who to contact may not always be clear. (See also: **D.4.4. Regulator engagement strategy**, M12)

<sup>1</sup> <https://www.esgct.eu/heatmap>

<sup>2</sup> <https://atmpsweden.se/product-development/partnering-and-companies/atmp-map/>

<sup>3</sup> [https://www.restore-horizon.eu/documents/deliverables/D1.4\\_final.pdf](https://www.restore-horizon.eu/documents/deliverables/D1.4_final.pdf)

<sup>4</sup> <https://www.ejparediseases.org/what-is-it/>

<sup>5</sup> <https://directory.bbmri-eric.eu/menu/main/app-molgenis-app-biobank-explorer#/>

<sup>6</sup> <https://atmpmanufacture.org/>

<sup>7</sup> <https://monitor-industrial-ecosystems.ec.europa.eu/technology-centre/mapping>

- The second group of actors which have not been included in the previous maps is the patient organisations actively involved in GCT development at various stages of the development pathways in different ways. Some are actively involved in supporting the research and development effort, while some are supporting the commercialisation aspect. Despite their active involvement, many regional and local patient organisations' information may not always be accessible to the GCT community and the public.

To address the missing gaps, EuroGCT sought to identify and map these actors' information within our Actors and Networks database, and to make such information accessible and freely available to anybody visiting [www.eurogct.org](http://www.eurogct.org).

We note that the limited span of the EuroGCT funding period, and the human resource available for this mapping activity, have limited the scope of our Actors and Networks map to mainly focus on capturing information that: i) has not been reported elsewhere, and ii) is long-lasting information that does not require frequent updates. Hence, the first iteration of this database does not yet include commercial partners and service providers. The first iteration of EuroGCT's Actors and Networks database will provide information complementary to ESGCT's existing heatmap, through depicting the European stakeholders supporting the development of GCTs.

## 2.2. Information organisation

Below we explain how we set out to establish the framework for organising information for the European GCT actors on our website.

The information on GCT stakeholders is vast and mapping it onto a database requires careful planning on the content presentation, both structurally and functionally. Moreover, the nature of the information for actors is structurally complex—actors may have multiple functions and work at various stages of GCT development—at the same time, this organised information needs to make sense and remain findable by users. This presents a great challenge and a need in web development on features to support this complex information organisation and presentation.

To address such challenge, we adopted a similar approach as the information organisation for the Research Pathways (<https://www.eurogct.org/research-pathways>, see **D4.1 Landscape Mapping**, M36). Built with the open-source content manage system Drupal, the database is readily scalable and expandable with customisable features. The initial version of this map is presented as an interactive, filterable and searchable database (Figure 2). Additional features and data entries can be iteratively added as the project progresses.

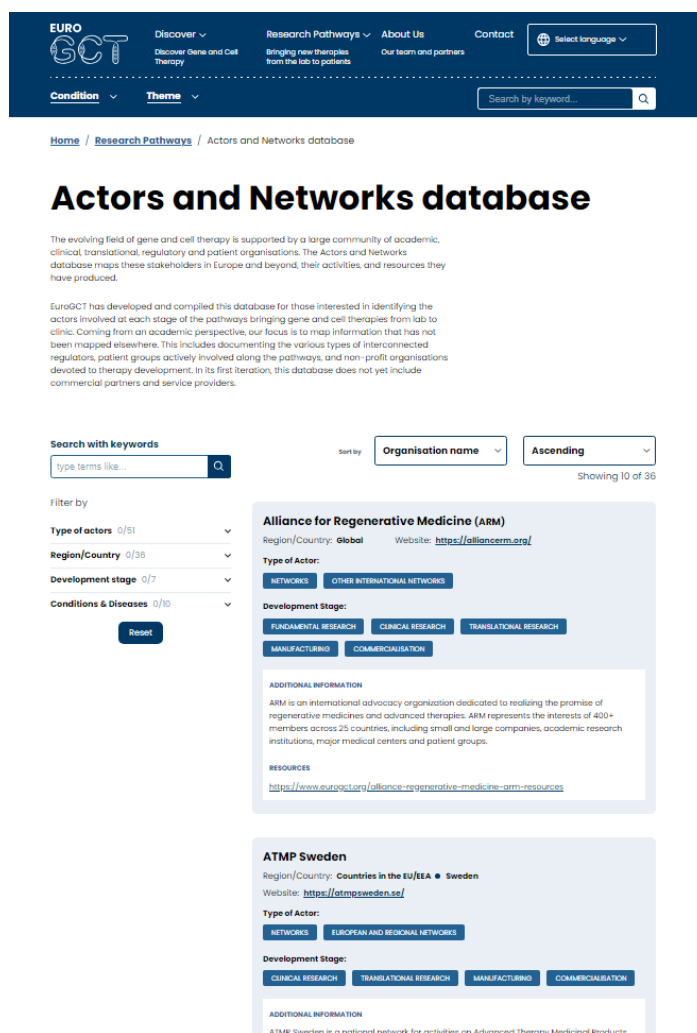


Figure 2. Screenshot of the Actors and Network Database page (cropped).

- **Tagging with taxonomy terms**

Organising information for the vast GCT actors requires thoughtfully designed taxonomies for categorising (tagging) each entry, and for pulling the tagged entries when a specific search filter is applied. The IMHT has first categorised the GCT actors by four main filters/entry points: i) the type of actors based on their function, ii) the region/country the actor is active in, iii) the development stage their activities are involved in, and iv) the conditions and diseases the actor is working on where relevant. It aims to cover the various interests of the map users and different ways they look up relevant information. We've then further subcategorised these four entry points accordingly, and it resulted in the full set of taxonomy terms as the following:

A. Type of actors

a. Regulators

- Medicines Agencies:
  - Supranational medicines Agencies
  - National medicines Agencies:
- HTA Bodies

- Ethics Committees
    - Supranational Ethics Bodies
    - National Ethics Committees
    - Research Ethics Committees
  - Medical Devices Entities
    - Medical Device Authorities
      - ♣ Supranational authorities
      - ♣ National authorities
    - Notified Bodies
  - Patent Offices (\*remit can go beyond patents and often relates to intellectual property in general)
    - Supranational offices
    - National offices
  - Data Authorities
    - Supranational authorities
    - National authorities
    - Regional/Local authorities
  - Research Funding Authorities
    - Supranational Authorities
    - National Authorities
  - Payers
  - Other National competent authorities:
    - Competent Authorities for Tissues and Cells
    - Competent Authorities for Blood and Blood Components
    - Competent Authorities for Animals
    - Competent Authorities for GMO
    - Competent Authorities for Research
- b. Networks
- National and International Societies
  - European and Regional Networks
    - European Research Infrastructures
    - European Reference Networks
  - EU Research Projects
  - Other International Projects
- c. Academic and non-profit Research Institutions and Organisations
- Universities
  - Foundations
  - Research Hospitals
  - Biobanks
- d. Patient Organisations
- European level
  - Regional
- e. Training Providers
- For medicines research and development
  - For patient involvement

- For Health data
- f. Publisher

- Journals

B. Region/Country

- EU
- EU Member State
  - France
  - Germany
  - Italy
  - Spain
  - Netherlands
  - ...(List all EU/EEA countries)
- UK
- USA
- Global
- Other

C. Development stage

- Fundamental Research
- Clinical research
- Translational Science
- Manufacturing
- Commercialisation

D. Conditions and Diseases

- Blood disorders
- Skin
- Eye disease
- Immune conditions
- Muscle and Skeletal Diseases
- Heart disease
- Rare diseases

The **Type of Actor** filter contains the category of actors with sharing similar functions. The categorising of regulator types has not been reported elsewhere but knowing who the regulators are and what their remit is essential information for those concerned in developing GCTs. Likewise, many regional and local patient organisations are involved and supporting GCT research and development efforts, but their information may not always be accessible. This list of “type of actors” can be further expanded as needed, for example, to include industry, service providers or individual laboratories when the set of taxonomy terms is determined for such actors at a later point.

The **Region/Country** filter concerns the geo- and political regions the actor is active in. For example, if an actor's activity is within an EU Member State, it will be tagged with the ‘Countries in the EU/EEA, country name’ tag. For actors who are active across all EU/EEA, it will be tagged with the ‘EU/EEA’ tag.

The **Development Stage** filter allows users to search for actors working on at one or more stage of GCT development.

The **Conditions and Diseases filters** can be utilised for users to search for patient organisations or developers of medicinal products related to specific types of condition or diseases when this information is available. This list of Conditions and Diseases can be expanded as needed.

- **Enhanced User Experience**

To improve user experience in their searches, we introduced search functions including search by keywords, and checkboxes to apply filters to the taxonomy terms, and implemented the sorting by field and order.

The “search by keywords” can be used for users to search for specific information such as types of technology, cell lines and more when such information is provided.

We anticipate the improved searchability and usability will greatly enhance users’ experience in searching and navigating within the section, and in turn improve engagement and learning.

### **2.3. Data Entry**

As the field of GCT evolves, the stakeholders’ information is anticipated to change over time. Hence, the Actors and Networks database has adopted a custom-designed bulk upload function. All actor’s information is compiled to a spreadsheet and then uploaded to the site in bulk. This saves time for managing existing data as well as adding new entries.

The EuroGCT IMHT has currently populated the Actors and Networks database with an initial set of actors based on the information collated with methodology listed in **D4.7**. We have then developed an online questionnaire (<https://app.onlinesurveys.jisc.ac.uk/s/edinburgh/actors-networks>) for the European stakeholders to determine how their organisations’ information is represented in this database. The information we are collecting through this questionnaire includes the categories within the taxonomy terms (see section 2.2 above) plus an additional hidden keywords field. Searches will be performed in this field which consists of the keywords supplied by actors themselves. This keyword field can be used in many ways, such as for actors to promote their techniques, capabilities, facilities, and additional resources they’ve produced.

We are currently in the process of distributing this questionnaire within our network and at events. The results collected will continue to be compiled and uploaded to the site during the span of the project.

## **3. Conclusion and future steps**

EuroGCT has developed an indexed catalogue of actors in the GCT field in Europe through the following:

- 1) determined the scope of actors to include in the first iteration of the stakeholders’ map
- 2) developed a set of taxonomy terms for organising actors’ information and to facilitate user searches;

- 3) built the Actors and Networks database with compatibility for future feature expansions;
- 4) added an initial set of identified actors;
- 5) launched an online questionnaire for actors to determine how their information can be represented in this database.

The above output is published on EuroGCT's website in the Actors and Networks section (<https://www.eurogct.org/research-pathways/actors-and-networks-database>) as a searchable and filterable database with direct links to actors' own websites and relevant resources. All contents within will continually be updated throughout the course of the project.

Through our links with ESGCT, we find there is a strong interest in making a comprehensive list of industrial actors, commercial partners and service providers accessible through our website. We anticipate our Actors and Networks database serves as a starting point for a collaboration to begin. As features and entries in this database be iteratively expanded, it becomes a valuable resource for the larger European gene and cell therapy community. Collaborating with ESGCT, the Actors and Network database should establish a valuable source of information for stakeholders interested in this innovative field where transformative therapies bring new hope for patients with unmet medical needs.