PRECISEU

D5.1 State-of-the-art of ATMP value chain

Capacity mapping of the ATMPs value chain, including existing initiatives, relevant technologies, technologies owner and key opinion leaders

EATRIS

30/06/2025

Co-funded by the European Union

This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301

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CONSORTIUM PARTNERS

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2	DEPARTAMENT DE SALUT- GENERALITAT DE CATALUNYA	SALUT	BEN	ES
3	BARCELONA SUPERCOMPUTING CENTER CENTRO NACIONAL DE SUPERCOMPUTACION	BSC-CNS	BEN	ES
4	BIORN CLUSTER MANAGEMENT GMBH	BIORN	BEN	DE
5	BIOPRO BADEN-WUERTTEMBERG GMBH	BIOPRO	BEN	DE
6	AGENTIA PENTRU DEZVOLTARE REGIONALA NORD-EST	NE RDA	BEN	RO
7	ASOCIATIA DIGITAL INNOVATION ZONE ZONA DE INOVARE DIGITALA	DIZNE	BEN	RO
8	CLUSTERUL REGIONAL INOVATIV DE IMAGISTICA MOLECULARA SI STRUCTURALA NORD-EST (IMAGO-MOL)	IMAGO-MOL	BEN	RO
9	BIOTEHNOLOGICHEN I ZDRAVEN KLASTER	HLSCB	BEN	BG
10	STOLICHNA OBSHTINSKA AGENTSIA ZA PRIVATIZATSIA I INVESTITSII	SIA	BEN	BG
11	CLUST ER INDUSTRIE DELLA SALUTE E DEL BENESSERE	CLUST ER	BEN	IT
12	REGIONE EMILIA ROMAGNA	RER	BEN	IT
13	ART-ER-SOCIETA CONSORTILE PER AZIONI	ART-ER	BEN	IT
14	VLAAMSE GEWEST	EWI	BEN	BE
15	MEDVIA	MEDVIA	BEN	BE
16	VIESOJI ISTAIGA INOVACIJU AGENTURA	IA LITHUANIA	BEN	LT
17	BRG, BUSINESS REGION GOTEBORG AB	BRG	BEN	SE
18	EATRIS ERIC	EATRIS	BEN	NL
19	PLATAFORMA DE ORGANIZACIONES DE PACIENTES	POP	BEN	ES
20	AGENCIA PER A LA COMPETITIVITAT DE LA EMPRESA	ACCIO	BEN	ES
21	IDRYMA TECHNOLOGIAS KAI EREVNAS	FORTH-ICS	BEN	EL
22	REGION OF CRETE	CRETE	BEN	EL
23	SAHLGRENSKA SCIENCE PARK AB	SSP	BEN	SE
24	RIVNE INTERREGIONAL MEDICAL CLUSTER	RIVNE	BEN	UA
25	ASTRAZENECA FARMACEUTICA SPAIN S.A.	ASTRAZENECA	BEN	ES

Tab. 1 The PRECISEU'S Consortium

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WORK PACKAGES AND LEADERS

Work Packages Name		WP Leader
WP 1	Project Management and Coordination	Biocat
WP 2	Communication and Dissemination	NE RDA
WP 3	Interregional Collaboration and Partnership Bridging	IA Lithuania
WP 4	Use of Health Data	ART-ER
WP 5	Multistakeholder infrastructure to enable access to ATMP on large scale	BIO PRO
WP 6	Market and Patient Access	SSP
WP 7	Training and Cultural Change	HLSCB
WP 8	Adoption of PM innovations in the HealthCare System	SALUT
WP 9	Innovation Support Program	Biocat

Tab. 2 The PRECISEU'S Work Packages

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EXECUTIVE SUMMARY

EATRIS, in collaboration with European partners and as part of the EU-funded PRECISEU project, is leading a **groundbreaking initiative to map Advanced Therapy Medicinal Product (ATMP) capacities across Europe**. This effort addresses a critical need to build a coordinated, data-driven infrastructure that ensures equitable access to Advanced Therapy Medicinal Products (ATMPs) including gene therapies, cell-based treatments, and tissue-engineered products, personalised medicine treatments that are reshaping modern medicine by providing therapeutic options to patients with unmet medical needs.

Despite rapid scientific progress, delivery of ATMPs remains uneven across EU Member States due to disparities in infrastructure, regulation, and clinical capabilities. This mapping initiative is designed to provide a new structured process that aims to capture within the timeframe of the PRECISEU project and beyond, a sustainable ATMP mapping process which will be maintained by EATRIS and partners as part of the infrastructure operations. This process now established within PRECISEU and outlined in this deliverable, aims to prospectively capture a comprehensive overview of the current landscape, identifying both strengths and critical gaps across:

- Academic and translational research centres
- GMP manufacturing and processing facilities
- Clinical trial sites and hospitals
- National regulatory and logistics frameworks

The results will inform strategic policy and investment decisions, support capacity building in under-served regions, and enable smarter collaboration between public and private stakeholders. By aligning efforts across countries and sectors, the initiative strengthens Europe's readiness to deliver cutting-edge therapies efficiently and equitably.

The key benefits of this ATMP mapping process includes:

- Accelerated clinical trial planning and site selection
- Enhanced cross-border collaboration and regulatory harmonization
- Improved patient referral pathways and access to treatment
- Stronger foundations for long-term competitiveness in the ATMP field

This mapping process will serve as both a current-state snapshot and a strategic planning tool to guide future funding, policy development, and health system readiness for personalised medicine development across Europe.

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INTRODUCTION

OBJECTIVES OF THE WP AND TASK

WP5 is dedicated to identifying key bottlenecks and improving access to ATMP infrastructures and resources across Europe. By enhancing visibility of existing capabilities and fostering stronger connections between stakeholders, WP5 aims to create a collaborative, well-integrated ATMP ecosystem. It supports the exchange of knowledge, the linking of established hubs, and the creation of new centres of excellence where needed. Key objectives include accelerating the development and delivery of safer, more effective gene therapies, particularly for rare diseases and high-need indications, and shortening the path from research to market. The initiative also addresses critical gaps in education, awareness, and regulatory understanding across the ATMP value chain, supporting developers, clinicians, regulators, and patients alike. By bridging the skills gap with targeted training programs, it lays the foundation for a more capable and future-ready ATMP workforce.

Task 5.1 aims to review the state of the art of ATMPs development and production in an EU major initiative which under D5,1 establishes a first sustainable process in the EU to map the capacities for developing and delivering Advanced Therapy Medicinal Products (ATMPs) across Europe. This strategic effort aims to play a critical role in improving patient access, accelerating clinical development, and building a more cohesive and innovative European ATMP ecosystem. As ATMPs, in particular cell and gene therapies, rapidly move from the lab to the clinic, Europe's ability to support their development and equitable delivery depends on understanding where expertise, infrastructure, and readiness exist. The EATRIS-led mapping survey, which was developed with support from the European Medicines Agency (EMA), addresses this need by assessing academic centers, GMP and Pre-GMP manufacturing sites, clinical trial hubs, and regulatory support amongst other critical capacities in ATMP translation throughout Europe.

CONTENTS OF THE MAPPING

ATMP CAPACITY MAPPING SURVEY

The following section reproduces the survey sent or disseminated to a broad number of stakeholders (estimated thousands) through networks, websites and Linkedin with the link and the QR code displayed below

https://preciseu.eu/mapping-atmp-capacities-across-europe/

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PRECISEU eatris ATMP Sweden

QUESTIONNAIRE

- Do you agree that EATRIS shares the answers provided above with the European Medicines Agency for analysis of potential needs for offering support to researchers and developers from the not-for-profit or academic sector, and for potential public reporting, exclusively of aggregated data?
  - Yes: please fill in your email address
  - No

- Do you give your consent for EATRIS to publish your name, the organisation you work for, and your role in that organisation, in a publicly available platform (Google Maps or other similar platform) with the purpose of generating an interactive map showing ATMP facilities around Europe? EATRIS could share or transmit your data to a third party for the sole objective of fulfilling such purpose. We inform you that we may share this information with our partners in the PRECISEU project, to fulfil the stated purpose.
  - Yes
  - No

- Do you consider yourself to be an*
  - Academic involved in ATMP development/manufacture.
  - Private company involved in ATMP development/ manufacture.
  - Facility for development, manufacture, or delivery of ATMPs.
  - Clinician developing ATMPs.
  - Clinician treating patients with ATMPs.
  - ATMP dispensation/delivery centre/hospital.
  - Service/product provider.
  - Other: please explain

➢ Academic involved in ATMP development/manufacture (or related technology)

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- Principle Investigators name*
- URL for most relevant homepage (start with http) *
- Description of your ATMP relevant research, where relevant including ATMP type (gene/cell therapy/TEP), format (viral ex-vivo, autologous cell therapy etc.) and indication (max 100 characters including spaces).
- Location (Name of your organization, department, city, and country) e.g. Karolinska Institute, Department of Medical Biochemistry and Biophysics.
- Address for google pin.

- Through which pathway is/are the ATMP(s) you develop/manufacture provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)
  - Authorised/reimbursed treatment.
  - As part of a clinical trial
  - Under hospital exemption
  - Other national provision:
    Please elaborate your answer:

- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:
  - Quality development
  - Non-clinical development
  - Clinical pharmacology/Pharmacokinetics
  - Clinical development
  - Statistics/methodology
  - GMP manufacturing
  - Regulatory affairs
  - Market access (HTA, pricing and reimbursement)
  - Other: please specify ….
    Additional information:

- Which type of ATMP(s) do you develop/manufacture?

- What disease areas/indications do they target?

➢ <u>Private company involved in ATMP development/ manufacture.</u>

- Company AB Name
- URL for most relevant homepage (start with http) *

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- Description of your ATMP relevant products and/or services. Where relevant including product name, ATMP type (gene/cell therapy/TEP), format (viral ex-vivo, autologous cell therapy etc.) and indication (max 100 characters including spaces).

- Location (Name of your organization, department, city, and country) e.g. Medicon Village, Lund.
- Address for google pin.
- Through which pathway is/are the ATMP(s) you develop/manufacture provided to patients in your region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)
  - Authorised/reimbursed treatment.
  - As part of a clinical trial
  - Under hospital exemption
  - Other national provision:
    Please elaborate your answer:

- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:
  - Quality development
  - Non-clinical development
  - Clinical pharmacology/Pharmacokinetics
  - Clinical development
  - Statistics/methodology
  - GMP manufacturing
  - Regulatory affairs
  - Market access (HTA, pricing and reimbursement)
  - Other: please specify ….
    Please elaborate your answer:
- Which type of ATMP(s) do you develop/manufacture?
  What disease areas/indications do they target?

➢ <u>Facility for development, manufacture, or delivery of ATMPs</u>

- Facility name*
- URL for most relevant homepage (start with http) *
- Description of facility, where relevant, number and grade of clean rooms, QP, tissue establishment authorisation, MPA or IVO manufacture licenses, biobank (max 100 characters including spaces).
- Location (Name of your organization, department, city, and country) e.g. Medicon Village, Lund.
- Through which pathway is/are the ATMP(s) you develop, manufacture, or dispense provided to patients in your centre, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)

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- Authorised/reimbursed treatment.
- As part of a clinical trial
- Under hospital exemption
- Other national provision:
  Please elaborate your answer:

- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:
  - Quality development
  - Non-clinical development
  - Clinical pharmacology/Pharmacokinetics
  - Clinical development
  - Statistics/methodology
  - GMP manufacturing
  - Regulatory affairs
  - Market access (HTA, pricing and reimbursement)
  - Other: please specify ….
    Please elaborate your answer:
- Which type of ATMP(s) do you develop, manufacture, or dispense to patients?
  What disease areas/indications do they target?

➢ Clinician developing ATMPs (or relevant technologies)

- Clinician name*
- URL for most relevant homepage (start with http) *
- Description (max 100 characters including spaces). Indications treated, procedures relevant to ATMP, clinical trial numbers.
- Location (Name of your organization, department, city, and country) e.g. Karolinska University Hospital, Stockholm. *
- Address for google pin e.g. Solnavägen 9, Solna (not to be published) *
- Through which pathway is/are the ATMP(s) you develop/manufacture provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)
  - Authorised/reimbursed treatment.
  - As part of a clinical trial
  - Under hospital exemption
  - Other national provision:
    Please elaborate your answer:
- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:
  - Quality development

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- Non-clinical development
- Clinical pharmacology/Pharmacokinetics
- Clinical development
- Statistics/methodology
- GMP manufacturing
- Regulatory affairs
- Market access (HTA, pricing and reimbursement)
- Other: please specify ….

  Please elaborate your answer:

- Which type of ATMP(s) do you develop/manufacture? What disease areas/indications do they target?

➢ Clinician treating patients with ATMPs.

- Clinician name*
- URL for most relevant homepage (start with http) *
- Description (max 100 characters including spaces). Indications treated, procedures relevant to ATMP, clinical trial numbers.
- Location (Name of your organization, department, city, and country) e.g. Karolinska University Hospital, Stockholm. *
- Address for google pin e.g. Solnavägen 9, Solna (not to be published) *
- Through which pathway is/are the ATMP(s) you dispense provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)
  - Authorised/reimbursed treatment.
  - As part of a clinical trial
  - Under hospital exemption
  - Other national provision:

    Please elaborate your answer:
- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used (suggested OPTIONAL question for treating clinicians):
  - Quality development
  - Non-clinical development
  - Clinical pharmacology/Pharmacokinetics
  - Clinical development
  - Statistics/methodology
  - GMP manufacturing
  - Regulatory affairs
  - Market access (HTA, pricing and reimbursement)
  - Other: please specify ….

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Please elaborate your answer:

- Which type of ATMP(s) do you dispense to patients?
- What disease areas/indications do they target?

➢ ATMP dispensation/delivery center/hospital

- Hospital ATMP Center name*
- URL for most relevant homepage (start with http) *
- Description of ATMP center (max 100 characters including spaces). *
- Location (Name of your organization, department, city, and country) e.g. Karolinska University Hospital, Stockholm. *
- Address for google pin e.g. Solnavägen 9, Solna (not to be published) *
- Through which pathway is/are the ATMP(s) you dispense provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)
  - Authorised/reimbursed treatment.
  - As part of a clinical trial
  - Under hospital exemption
  - Other national provision:

  Please elaborate your answer:
- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:
  - Quality development
  - Non-clinical development
  - Clinical pharmacology/Pharmacokinetics
  - Clinical development
  - Statistics/methodology
  - GMP manufacturing
  - Regulatory affairs
  - Market access (HTA, pricing and reimbursement)
  - Other: please specify ….

  Please elaborate your answer:
- Which type of ATMP(s) do you dispense to patients?
  What disease areas/indications do they target?

➢ Service/Product Provider

- Name of company/researcher/clinician
- Please describe your ATMP relevant activity*
- URL for most relevant homepage (start with http) *
- Address for google pin e.g. Solnavägen 9, Solna (not to be published) *

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- Through which pathway is/are the ATMP(s) you develop, manufacture, or dispense provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)
  - Authorised/reimbursed treatment.
  - As part of a clinical trial
  - Under hospital exemption
  - Other national provision:
    Please elaborate your answer:
- Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement? If the answer is yes, please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:
  - Quality development
  - Non-clinical development
  - Clinical pharmacology/Pharmacokinetics
  - Clinical development
  - Statistics/methodology
  - GMP manufacturing
  - Regulatory affairs
  - Market access (HTA, pricing and reimbursement)
  - Other: please specify ….
    Please elaborate your answer:
- Which type of ATMP(s) do you develop, manufacture, or dispense to patients?
- What disease areas/indications do they target?

"Opt in" question at the end of the survey:
Do you agree to be contacted by EATRIS or the European Medicines Agency about ATMP related activities, studies, or events?

- Yes: please fill in your email address
- No

By submitting this form, I agree that my personal data may be processed by EATRIS in accordance with EATRIS *Privacy Policy* for the conduction of this survey and related actions to PRECISEU project (follow up communications, event reporting)
I agree that my personal data may be processed by EATRIS in accordance with EATRIS Privacy Policy *Privacy Policy* for the purpose of:
() EATRIS recording my personal data to be used for future project/collaboration opportunities with EATRIS or members of EATRIS infrastructure.
() receiving electronic communications on EATRIS news, events and activities

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Figure 1: Mapping Campaign launched by EATRIS

Survey Link: ATMP Capacity Mapping Survey

METHODS AND DATA SOURCES

METHODS

• Create a process to prospectively capture ATMP capacities over the coming years across PRECISEU regions, followed by EATRIS countries, followed by remaining EU countries.
• Create a survey by keeping it simple and capture the most important information.
• Create a marketing campaign to successfully survey all stakeholders in a continuous process over the project duration and beyond including inviting regional hubs as potential co-developers of the map and list them as contributors.
• Develop a process that will lead to not only the development of a first Pan-EU ATMP Capacity Map but a sustainable process to maintain it beyond PRECISEU where its integrated permanently in the EATRIS ATMP program and supported with the resources to do so.

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- Involve the European Medicines Agency for a survey that captures information critical to the regulatory process also and where the survey could be disseminated to the EMA stakeholder list regularly.

Figure 2 Capture the critical entities involved in ATMP development

DATA SOURCES

The Survey uses an open survey platform operated by EATRIS. By submitting this survey applicants must agree that their personal data may be processed by EATRIS in accordance with EATRIS *Privacy Policy* for the conduction of this survey and related actions to PRECISEU project (follow up communications, event reporting).

They can also agree if their personal data may be processed by EATRIS in accordance with EATRIS Privacy Policy *Privacy Policy* for the purpose of future project/collaboration opportunities with EATRIS or members of EATRIS infrastructure or receiving electronic communications on EATRIS news, events and activities.

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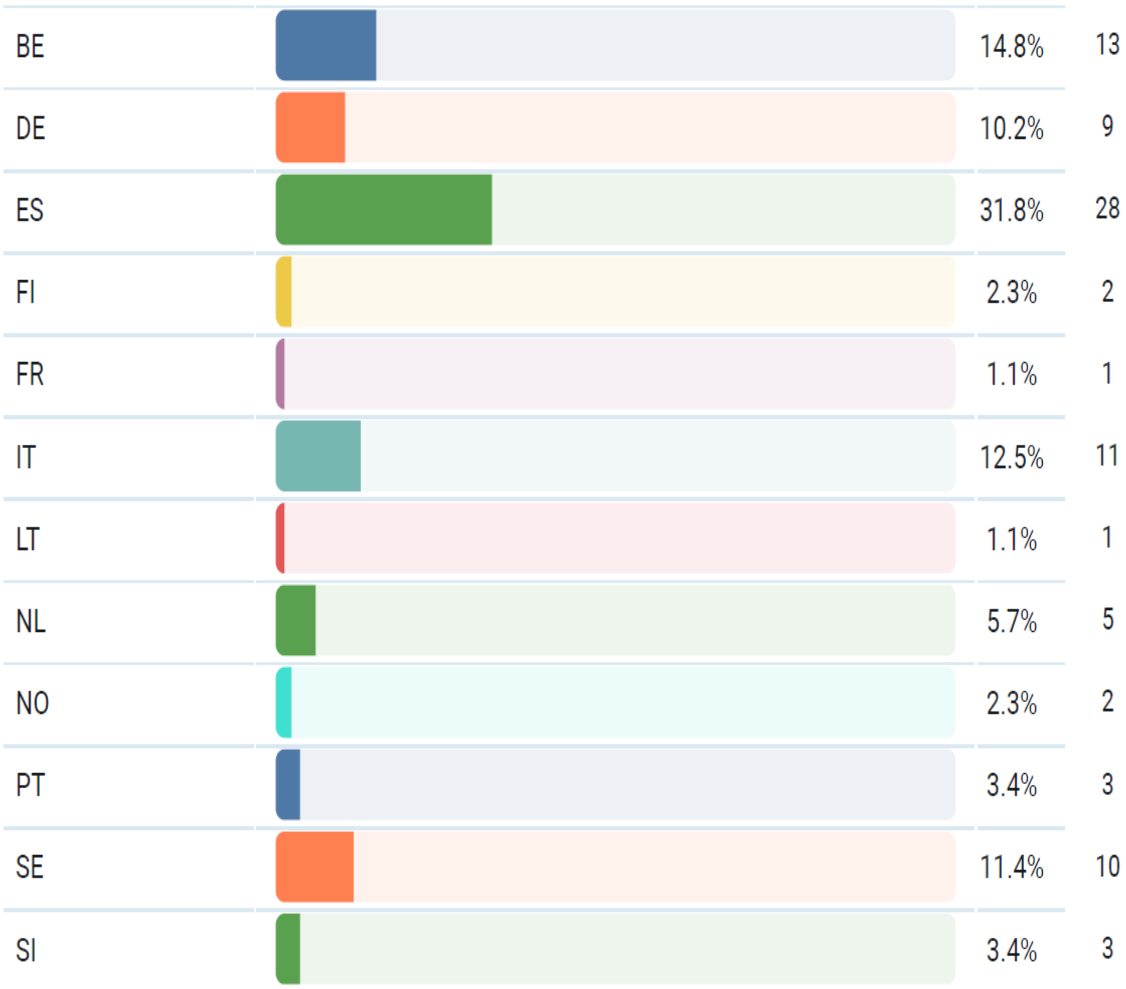

Figure 3- Data form the first survey launch (Version 0.1) consist of data from 88 respondents.

PRESENTATION OF RESULTS

The PRECISEU ATMP mapping process has now been successfully created and launched. This EU initiative aims to provide a detailed and actionable overview of ATMP capacities across Europe with the following domains:

- Academic and Translational Research Centers
- GMP Manufacturing and Processing Facilities
- Clinical Trial Sites and Hospitals
- National Regulatory Frameworks and Logistics Infrastructure

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ADVANTAGES FOR STAKEHOLDERS ACROSS THE ECOSYSTEM

Policy Makers and Funders

- Evidence-Based Decision-Making for targeted funding and capacity building
- Investment Prioritization in under-served regions to reduce health inequities.

Researchers and Academics

- Enhanced Cross-Border Collaboration through visibility of complementary capacities
- Efficient Use of Resources by avoiding duplication in capabilities and infrastructure

Industry and Developers

- Streamlined Supply Chain Design based on existing facilities and logistics hubs.
- Partner and Site Identification for clinical trials, production scale-up, and regulatory support

Hospitals and Clinical Trial Sites

- Benchmarking and Strategic Planning to align with EU-wide treatment and research goals.
- Patient Referral Optimization by mapping centers of excellence and treatment pathways

Patients and Advocacy Groups

- Increased Transparency and Equity in access to therapies
- Faster Enrollment in trials and early access programs via clear site visibility

OUTCOMES AND LONG-TERM IMPACT

This mapping initiative is more than a data collection exercise it is a strategic tool for future planning, investment, and policy alignment. The outcomes will:

- Inform national and EU-level decisions on ATMP strategy and funding.
- Accelerate the harmonization of regulatory and logistical frameworks.
- Enable efficient and inclusive clinical trial planning.
- Support smarter Public-Private partnerships and innovation ecosystems.

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This first of its kind initiative at this pan EU scale embodies PRECISEU's mission to operationalize precision medicine through harmonized, patient-centered innovation. It aims to serve as both a snapshot of current capacities and a forward-looking blueprint for Europe's leadership in ATMP development and access.

SAMPLE

We provide below the first examples of how the map will be presented to the public based on the first tranche of data received through this survey.

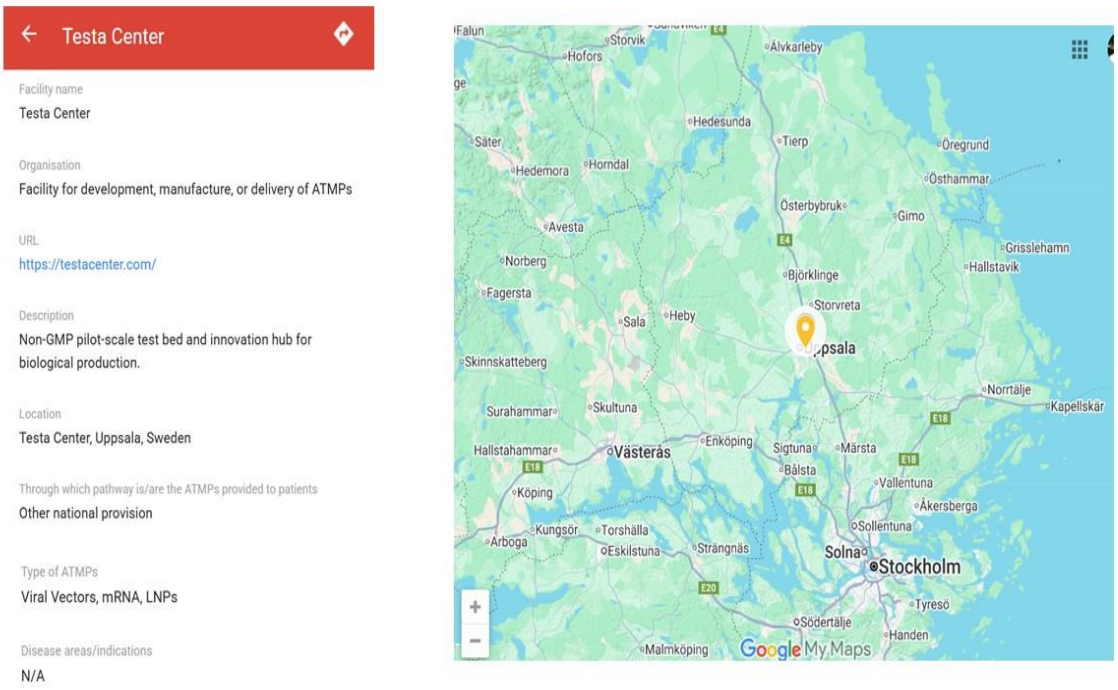

Figure 4- Example of an academic institution involved in ATMP development

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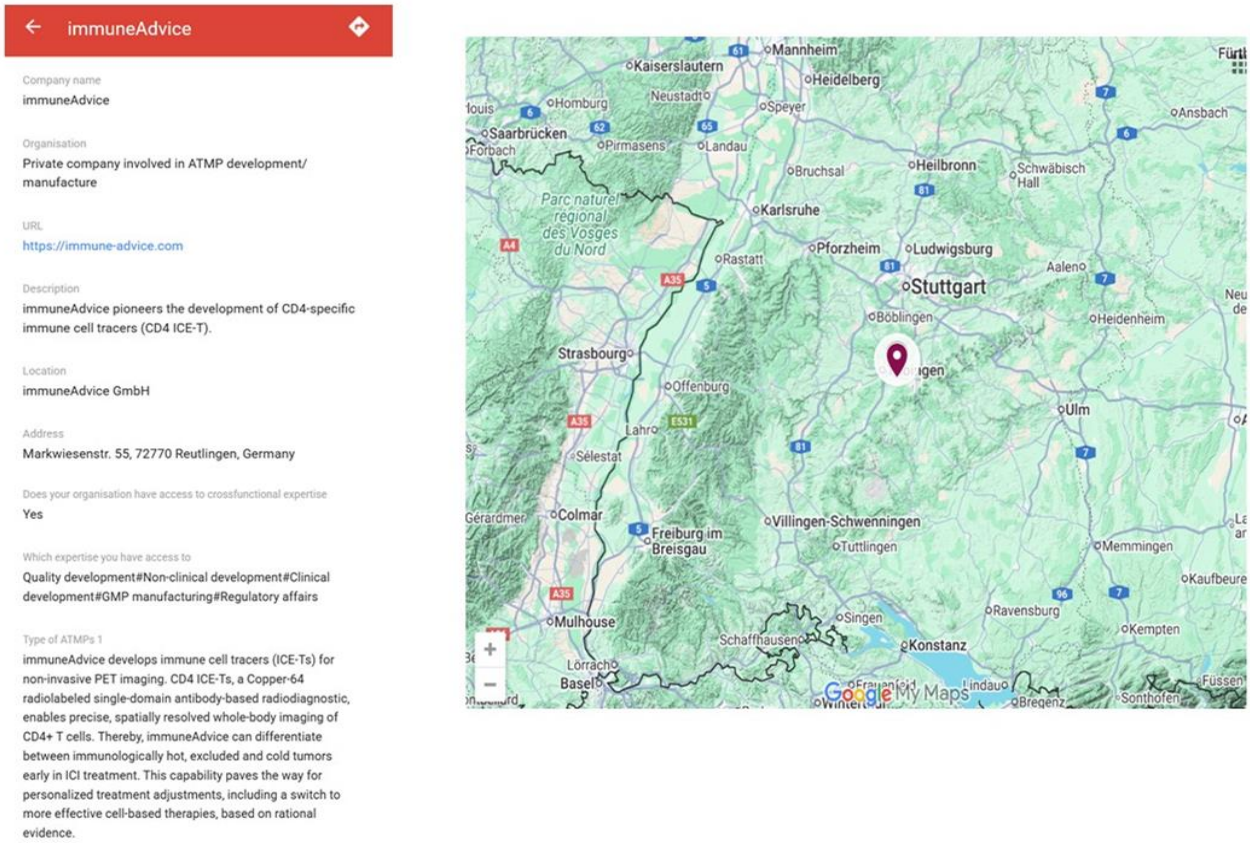

Figure 5- Example of Private Company involved in ATMP development

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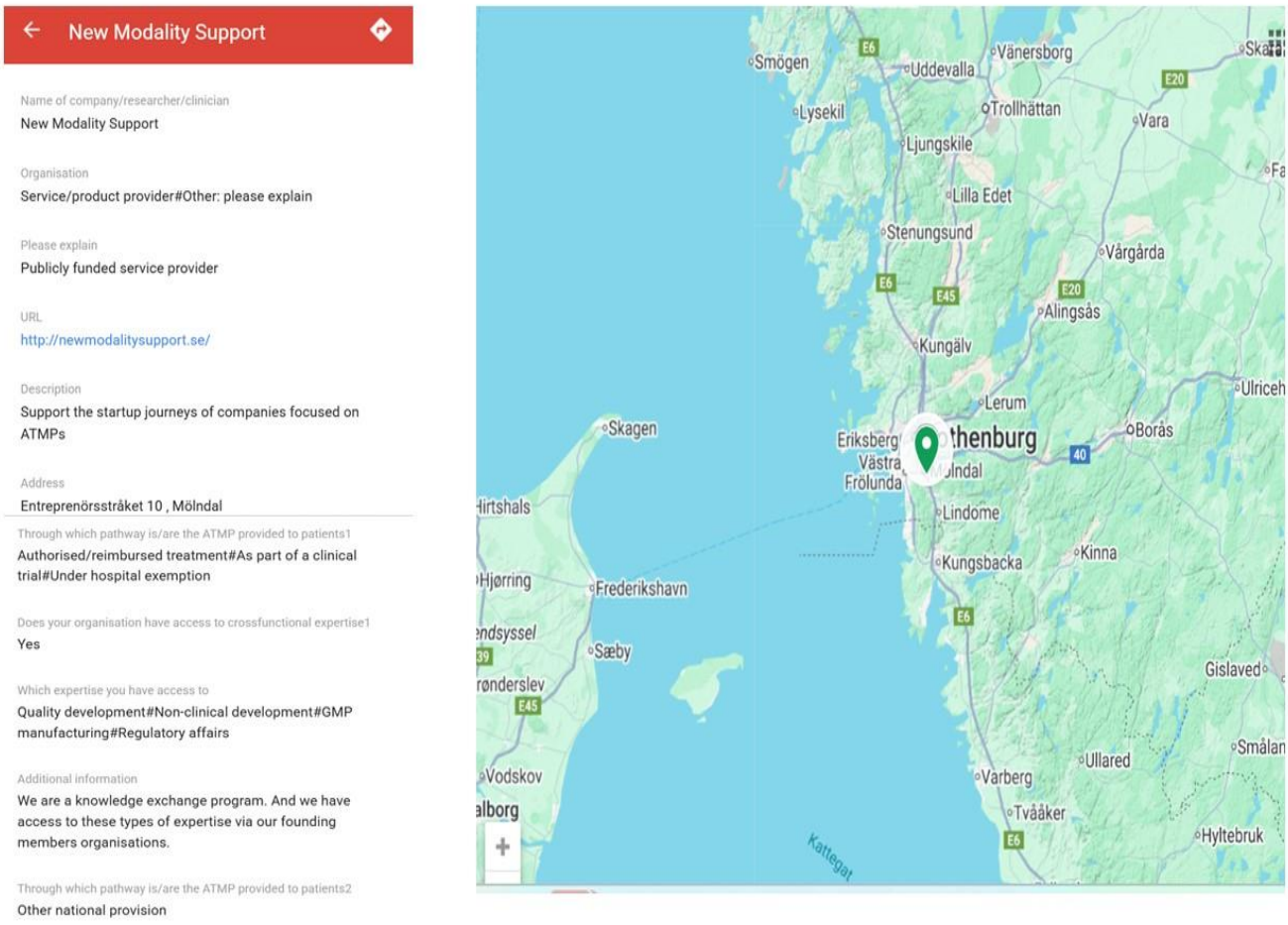


Figure 6- Example of a service provider involved in ATMP development

SUMMARY OF ONGOING ACTIVITIES

Deliverable D5.1, titled *"State-of-the-Art of the ATMP Value Chain"*, has successfully initiated a structured process to progressively map the capacity of the ATMP (Advanced Therapy Medicinal Products) value chain across Europe. This includes identifying current initiatives, key enabling technologies, technology owners, and relevant key opinion leaders (KOLs). A central focus of this deliverable was the establishment of a scientifically robust methodology developed with the support of the European Medicines Agency (EMA) to ensure enhanced granularity and utility. This process is designed to serve not only academic developers of ATMPs, but also private sector stakeholders and governmental bodies, ensuring broad applicability and impact.

Co-funded by the European Union
This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301

With the foundational mapping process now established, the PRECISEU project is preparing to launch the first live, interactive ATMP capacity map by the end of 2025. The initial dataset compiled for this deliverable includes responses from nearly 90 ATMP development groups spanning 12 EU countries. The next immediate steps involve identifying capacity gaps beginning with the PRECISEU regions to ensure a comprehensive dataset informs the first live release. In parallel, ATMP institutions across the 15 EATRIS member countries will be actively engaged and included in the mapping effort.

Once a critical mass of institutions is represented in the initial map, this will serve as the basis for a broader communications and outreach campaign. The campaign will aim to encourage participation from all EU-based ATMP developers.
To ensure industry participation, the mapping process will be exclusively promoted at international ATMP-focused conferences. Additionally, a dedicated promotional campaign will be conducted in prominent online journals such as *Cell and Therapy Insights*, where EATRIS holds a position on the editorial board.

This visibility will enable developers and stakeholders across the EU to access and contribute to a clear overview of ATMP development capacity and infrastructure.
It is important to understand that this initiative marks the beginning of a long-term, strategic journey to create the first pan-European ATMP capacity map. This deliverable has laid the groundwork by creating a scalable process and workflow that will remain a core mission of the PRECISEU project.
Moreover, the EATRIS ATMP Platform is committed to maintaining and continuously promoting the map for decades to come. This presents a realistic and sustainable model, in contrast to previous local initiatives that were unable to continue beyond initial funding periods.
Supported by partners like the EMA, PRECISEU will continue to strategize the success and expansion of the EU ATMP Capacity Map. By the project's conclusion, it aims to deliver a fully functional, comprehensive, and sustainable mapping tool that benefits all stakeholders in the ATMP development ecosystem.

At its core, the PRECISEU initiative is not only about data, but also about impact. This capacity mapping effort is a transformative enabler for ATMP developers, who will gain unprecedented visibility into Europe's therapeutic innovation landscape. It supports faster partnerships, informed decision-making, and equitable access to critical infrastructure across regions.
But more importantly, it is about accelerating the path from bench to bedside. By helping developers navigate and connect the European ecosystem more efficiently, this initiative aims to reduce time-to-clinic for cutting-edge therapies ultimately delivering hope and access to patients who need it most.
In supporting regional capacity-building, PRECISEU is also driving a more balanced innovation model across Europe ensuring that world-class therapeutic development is not limited to a few hubs but can flourish in diverse geographies. This is how PRECISEU delivers on its mission: to democratise innovation, empower developers, and bring life-saving therapies to patients, faster and more equitably.

This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301

Annex - ATMP Mapping Capacity Survey Results Overview

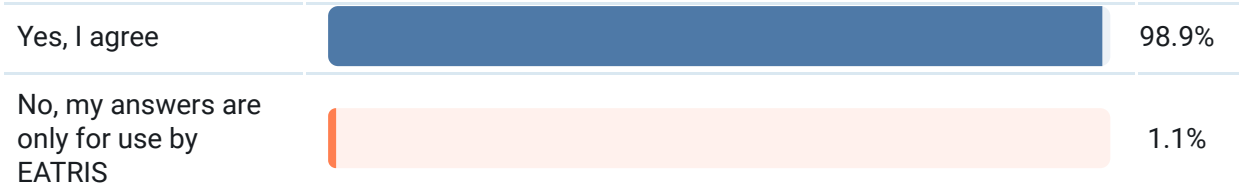
Co-funded by the European Union

This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101161301

ATMP Capacity Mapping Survey

Report generated on Jun 26, 2025, 1:45 PM

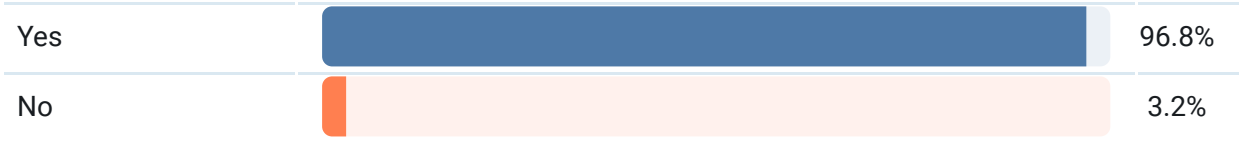
Do you agree that EATRIS shares the answers provided below with the European Medicines Agency for analysis of potential needs for offering support to researchers and developers from the not-for-profit or academic sector, and for potential public reporting, exclusively of aggregated data?



Yes, I agree	98.9%	94
No, my answers are only for use by EATRIS	1.1%	1

Total answers	95
Unique Respondents	95
Form respondents	95
Respondent Reach	100%

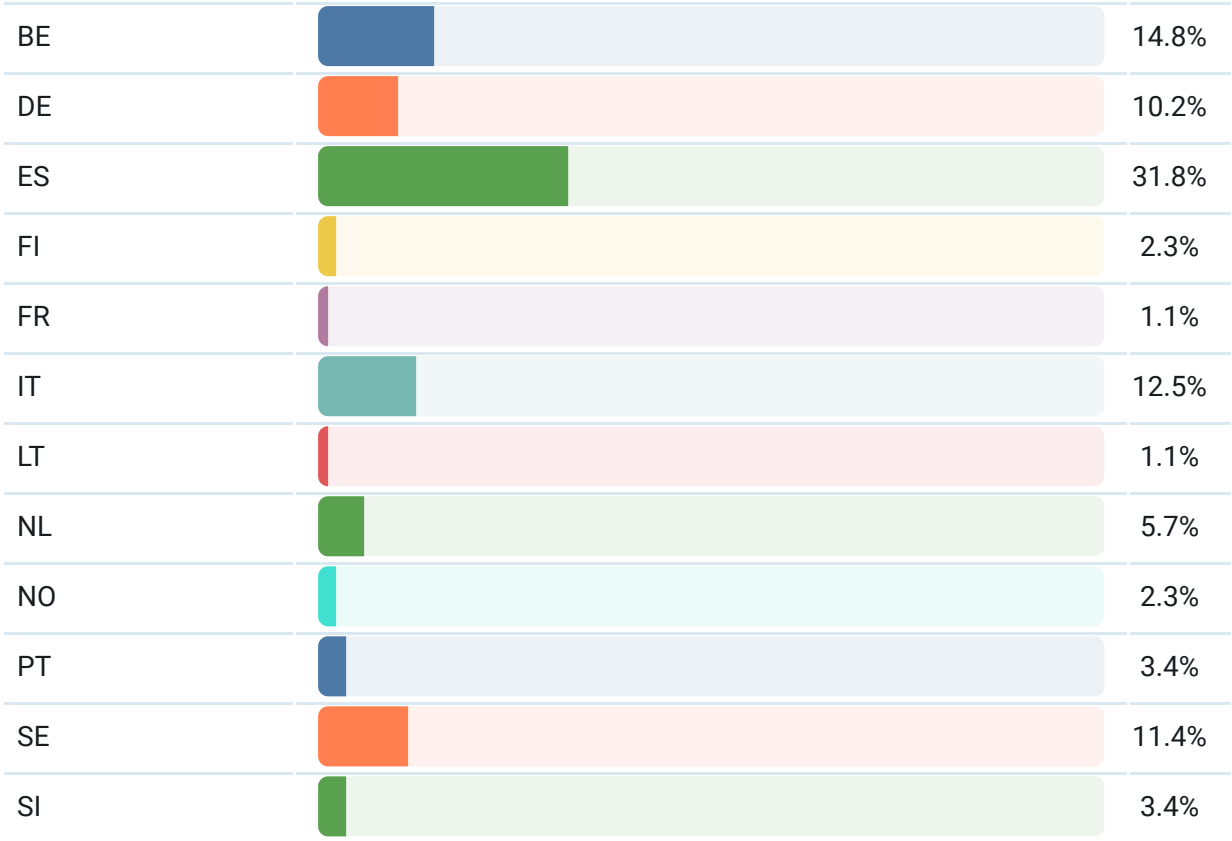
Do you give your consent for EATRIS to publish your name, the organisation you work for, and your role in that organisation, in a publicly available platform (Google Maps or other similar platform) with the purpose of generating an interactive map showing ATMP facilities around Europe? EATRIS could share or transmit your data to a third party for the sole objective of fulfilling such purpose. We inform you that we may share this information with our partners in the PRECISEU project, to fulfil the stated purpose.



Yes	96.8%	92
No	3.2%	3

Total answers	95
Unique Respondents	95
Form respondents	95
Respondent Reach	100%

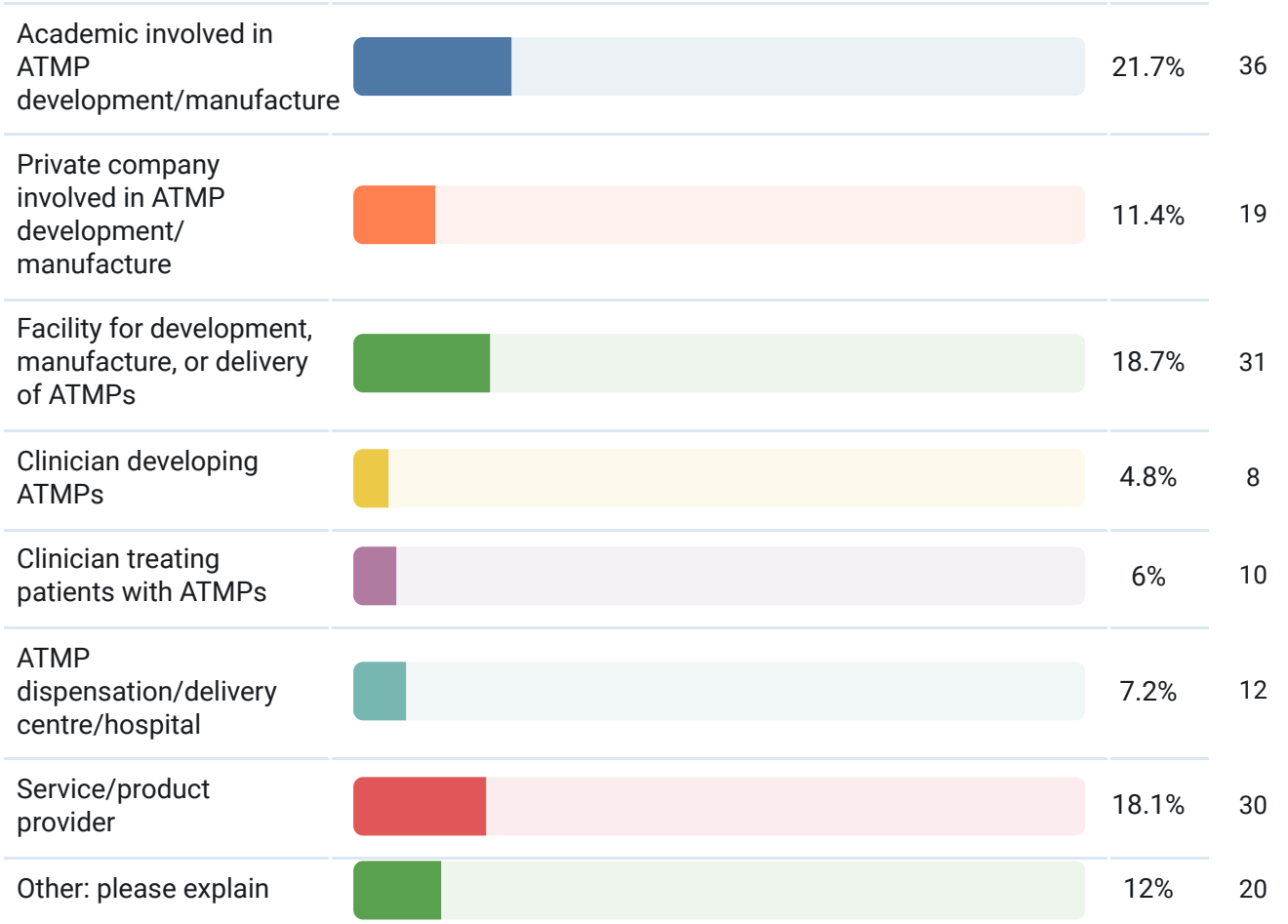
Please specify your country:



BE	14.8%	13
DE	10.2%	9
ES	31.8%	28
FI	2.3%	2
FR	1.1%	1
IT	12.5%	11
LT	1.1%	1
NL	5.7%	5
NO	2.3%	2
PT	3.4%	3
SE	11.4%	10
SI	3.4%	3

Total answers	88
Unique Respondents	88
Form respondents	95
Respondent Reach	92.6%

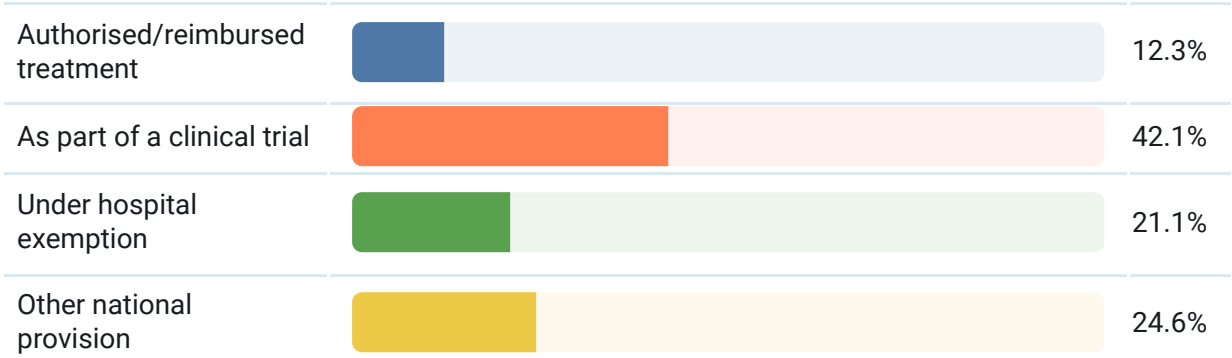
Do you consider yourself/your organisation to be:



Academic involved in ATMP development/manufacture	21.7%	36
Private company involved in ATMP development/ manufacture	11.4%	19
Facility for development, manufacture, or delivery of ATMPs	18.7%	31
Clinician developing ATMPs	4.8%	8
Clinician treating patients with ATMPs	6%	10
ATMP dispensation/delivery centre/hospital	7.2%	12
Service/product provider	18.1%	30
Other: please explain	12%	20

Total answers	166
Unique Respondents	95
Form respondents	95
Respondent Reach	100%

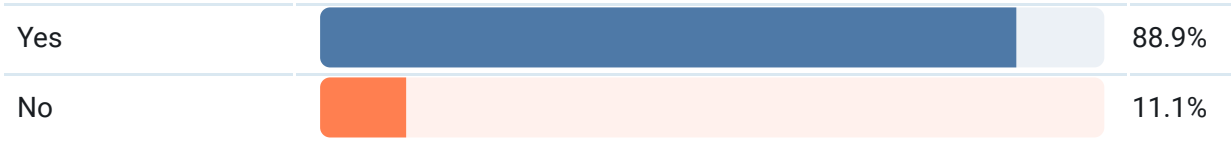
Through which pathway is/are the ATMP(s) you develop/manufacture provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	12.3%	7
As part of a clinical trial	42.1%	24
Under hospital exemption	21.1%	12
Other national provision	24.6%	14

Total answers	57
Unique Respondents	36
Form respondents	95
Respondent Reach	37.9%

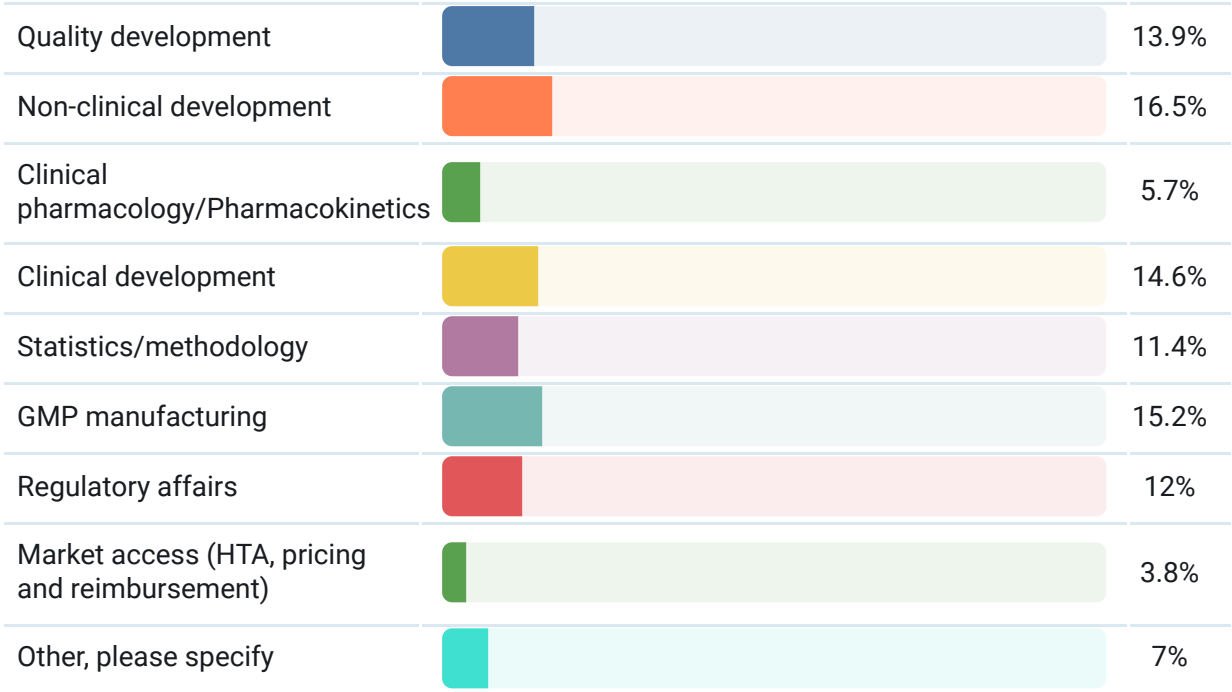
Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?



Yes	88.9%	32
No	11.1%	4

Total answers	36
Unique Respondents	36
Form respondents	95
Respondent Reach	37.9%

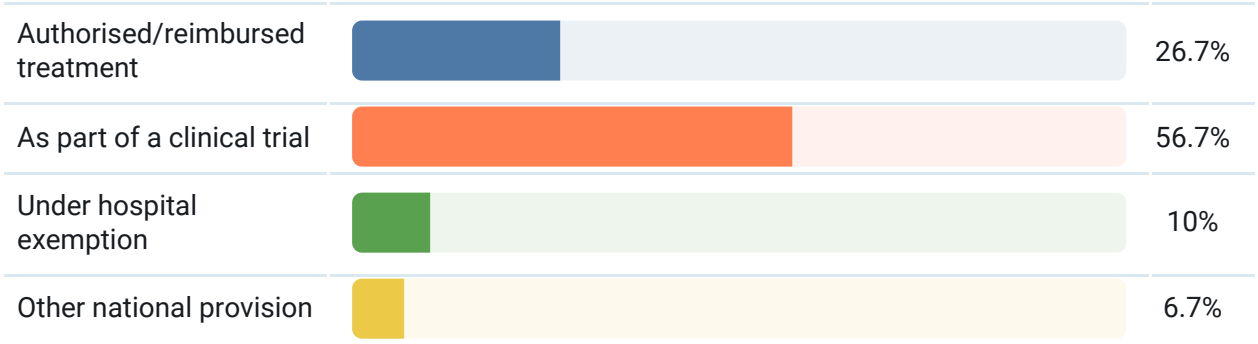
Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	13.9%	22
Non-clinical development	16.5%	26
Clinical pharmacology/Pharmacokinetics	5.7%	9
Clinical development	14.6%	23
Statistics/methodology	11.4%	18
GMP manufacturing	15.2%	24
Regulatory affairs	12%	19
Market access (HTA, pricing and reimbursement)	3.8%	6
Other, please specify	7%	11

Total answers	158
Unique Respondents	32
Form respondents	95
Respondent Reach	33.7%

Through which pathway is/are the ATMP(s) you develop/manufacture provided to patients in your region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	26.7%	8
As part of a clinical trial	56.7%	17
Under hospital exemption	10%	3
Other national provision	6.7%	2

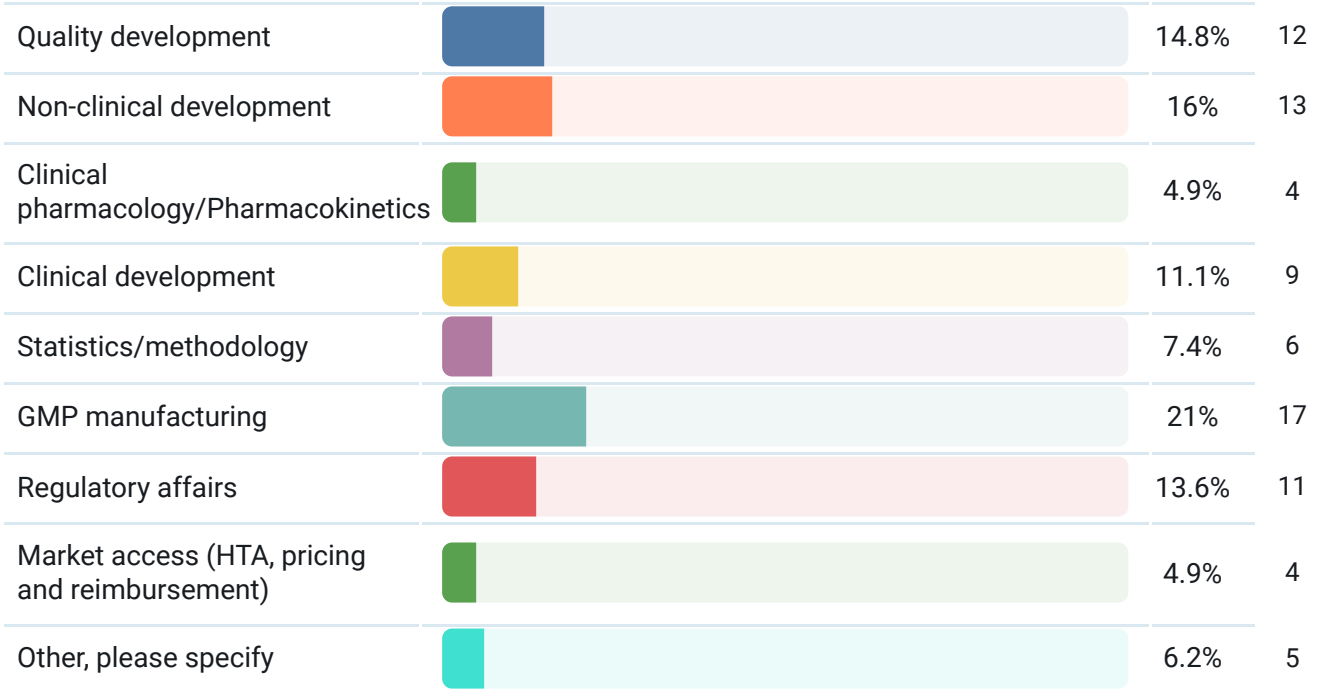
Total answers	30
Unique Respondents	19
Form respondents	95
Respondent Reach	20%

Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?

Yes	100%	19
No	0%	0

Total answers	19
Unique Respondents	19
Form respondents	95
Respondent Reach	20%

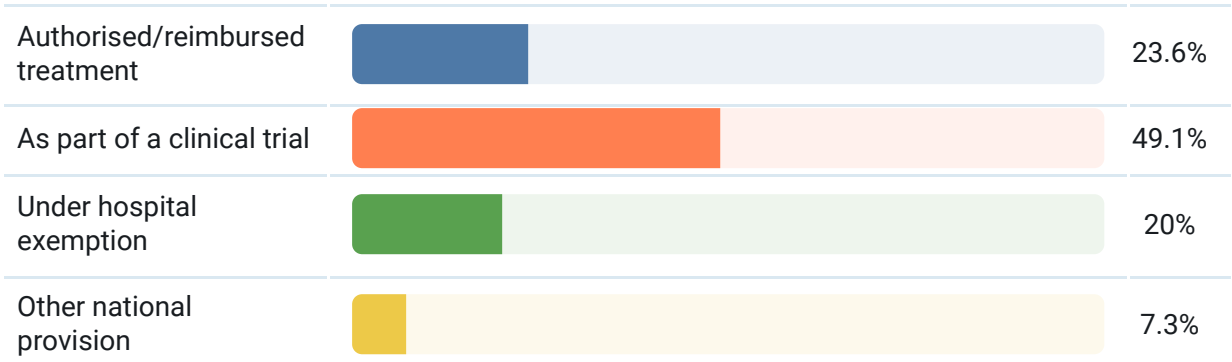
Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	14.8%	12
Non-clinical development	16%	13
Clinical pharmacology/Pharmacokinetics	4.9%	4
Clinical development	11.1%	9
Statistics/methodology	7.4%	6
GMP manufacturing	21%	17
Regulatory affairs	13.6%	11
Market access (HTA, pricing and reimbursement)	4.9%	4
Other, please specify	6.2%	5

Total answers	81
Unique Respondents	19
Form respondents	95
Respondent Reach	20%

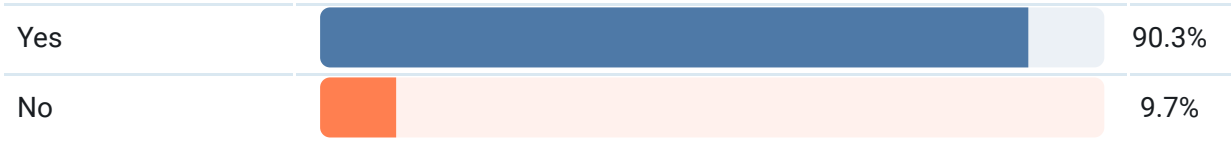
Through which pathway is/are the ATMP(s) you develop, manufacture or dispense provided to patients in your centre, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	23.6%	13
As part of a clinical trial	49.1%	27
Under hospital exemption	20%	11
Other national provision	7.3%	4

Total answers	55
Unique Respondents	31
Form respondents	95
Respondent Reach	32.6%

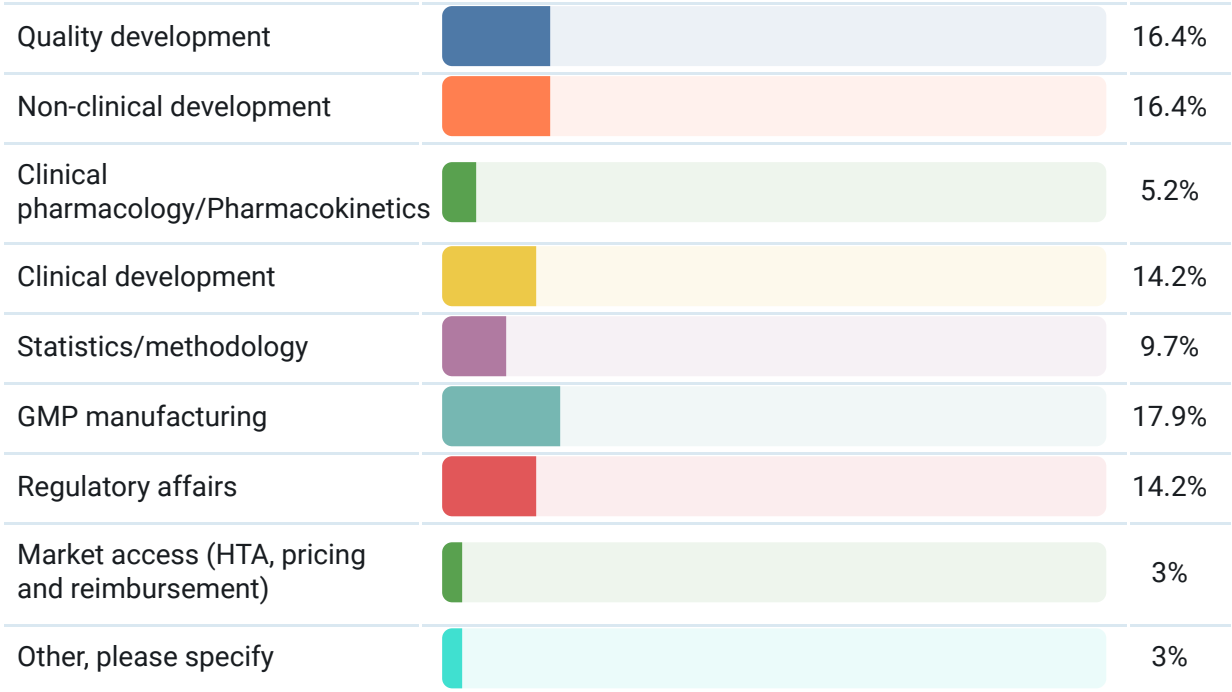
Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?



Yes	90.3%	28
No	9.7%	3

Total answers	31
Unique Respondents	31
Form respondents	95
Respondent Reach	32.6%

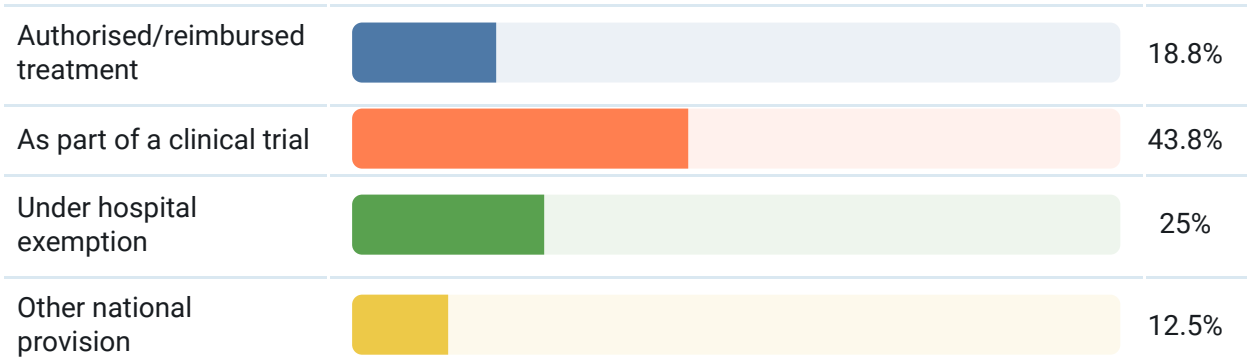
Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	16.4%	22
Non-clinical development	16.4%	22
Clinical pharmacology/Pharmacokinetics	5.2%	7
Clinical development	14.2%	19
Statistics/methodology	9.7%	13
GMP manufacturing	17.9%	24
Regulatory affairs	14.2%	19
Market access (HTA, pricing and reimbursement)	3%	4
Other, please specify	3%	4

Total answers	134
Unique Respondents	28
Form respondents	95
Respondent Reach	29.5%

Through which pathway is/are the ATMP(s) you develop/manufacture provided to patients in your centre, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



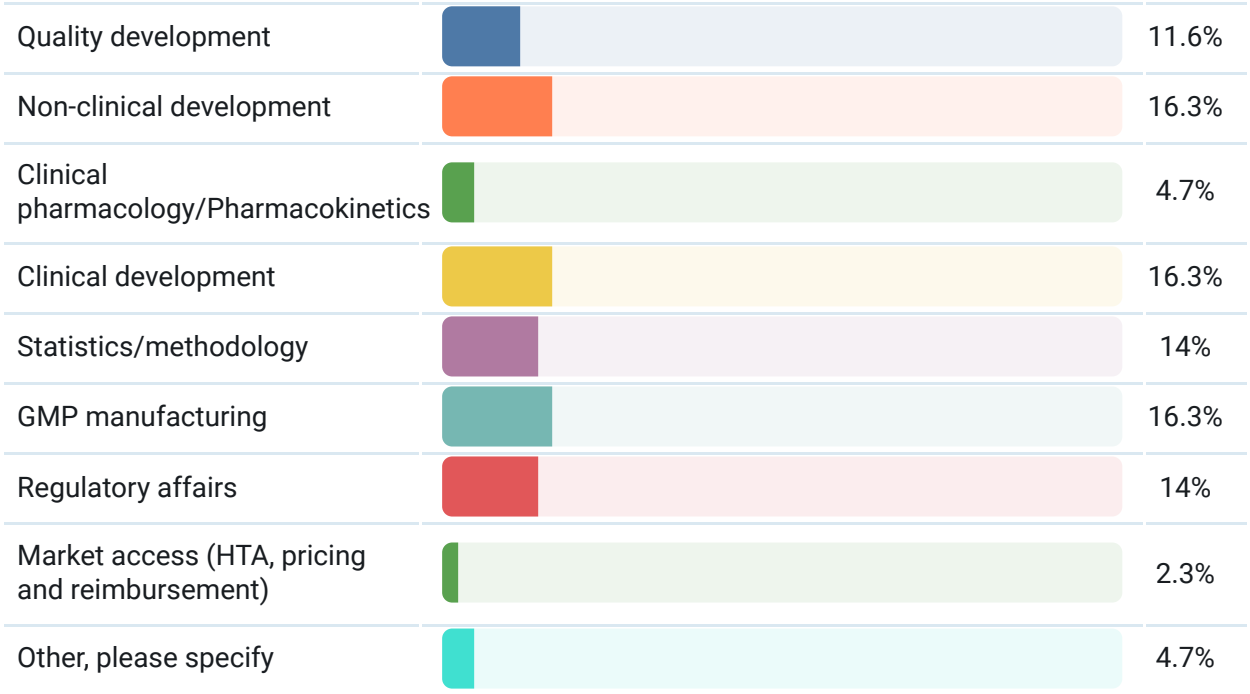
Authorised/reimbursed treatment	18.8%	3
As part of a clinical trial	43.8%	7
Under hospital exemption	25%	4
Other national provision	12.5%	2

Total answers	16
Unique Respondents	8
Form respondents	95
Respondent Reach	8.4%

Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?

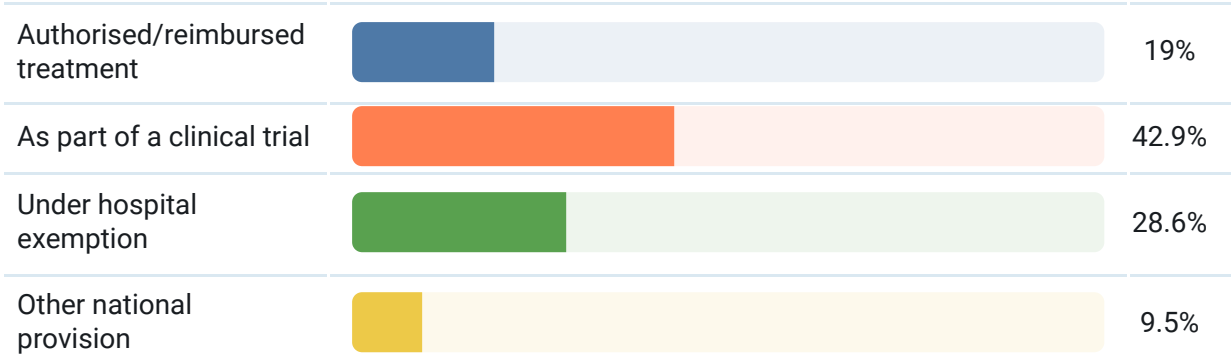
Yes	87.5%	7
No	12.5%	1
Total answers		8
Unique Respondents		8
Form respondents		95
Respondent Reach		8.4%

Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	11.6%	5
Non-clinical development	16.3%	7
Clinical pharmacology/Pharmacokinetics	4.7%	2
Clinical development	16.3%	7
Statistics/methodology	14%	6
GMP manufacturing	16.3%	7
Regulatory affairs	14%	6
Market access (HTA, pricing and reimbursement)	2.3%	1
Other, please specify	4.7%	2
Total answers		43
Unique Respondents		7
Form respondents		95
Respondent Reach		7.4%

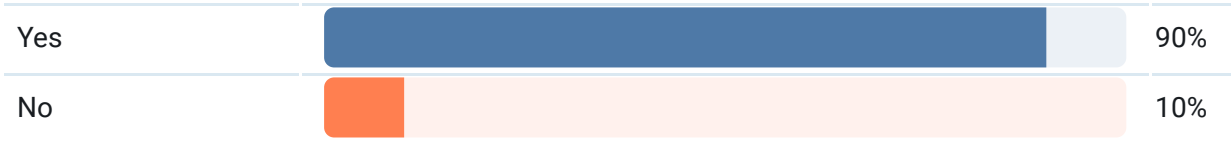
Through which pathway is/are the ATMP(s) you dispense provided to patients in your centre, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	19%	4
As part of a clinical trial	42.9%	9
Under hospital exemption	28.6%	6
Other national provision	9.5%	2

Total answers	21
Unique Respondents	10
Form respondents	95
Respondent Reach	10.5%

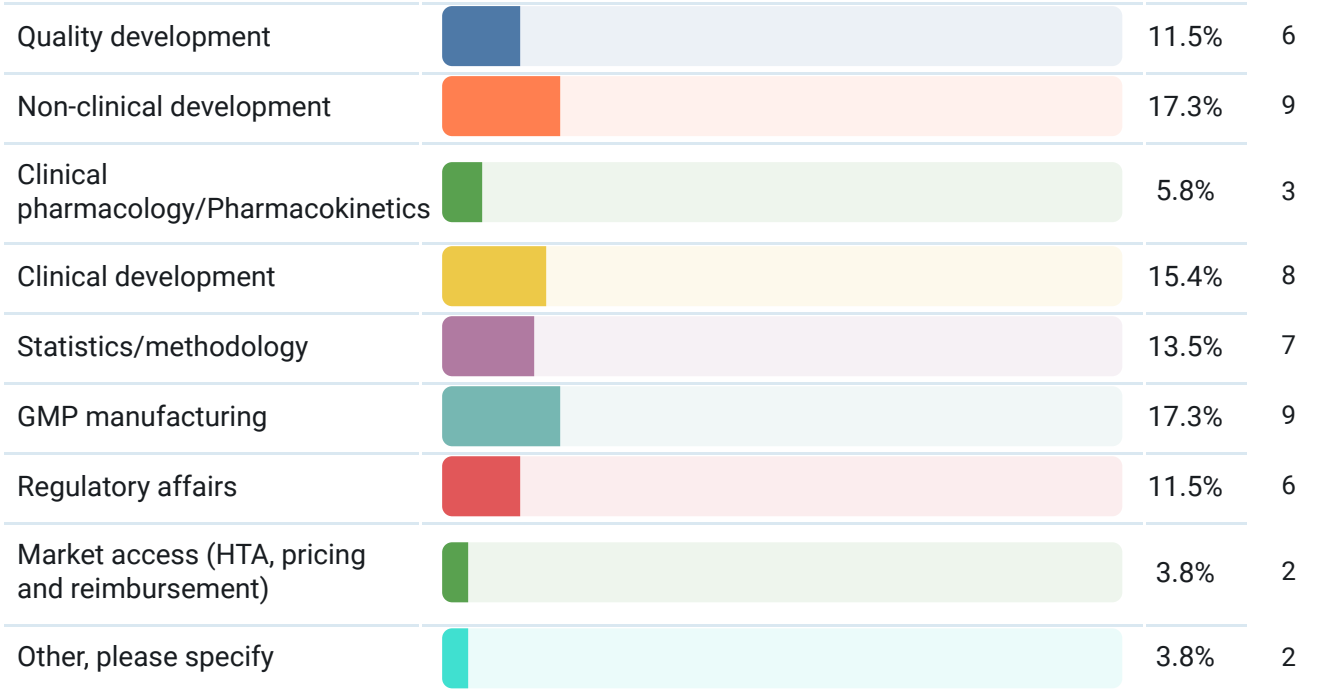
Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?



Yes	90%	9
No	10%	1

Total answers	10
Unique Respondents	10
Form respondents	95
Respondent Reach	10.5%

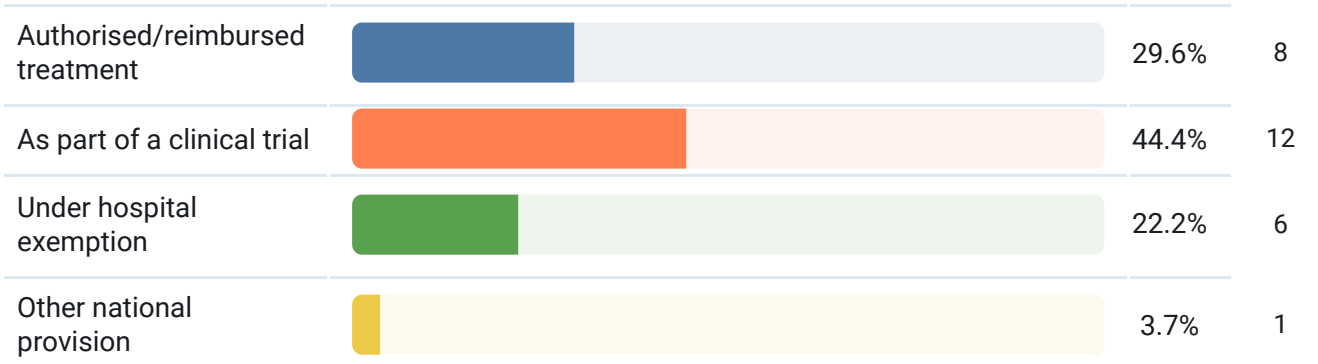
Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	11.5%	6
Non-clinical development	17.3%	9
Clinical pharmacology/Pharmacokinetics	5.8%	3
Clinical development	15.4%	8
Statistics/methodology	13.5%	7
GMP manufacturing	17.3%	9
Regulatory affairs	11.5%	6
Market access (HTA, pricing and reimbursement)	3.8%	2
Other, please specify	3.8%	2

Total answers	52
Unique Respondents	9
Form respondents	95
Respondent Reach	9.5%

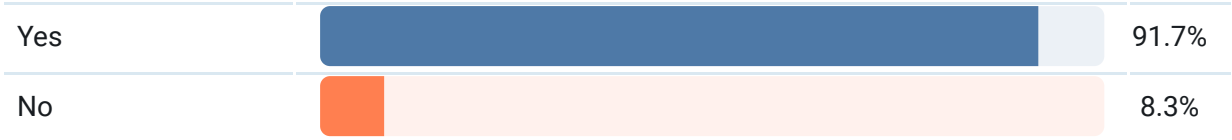
Through which pathway is/are the ATMP(s) you dispense provided to patients in your centre, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	29.6%	8
As part of a clinical trial	44.4%	12
Under hospital exemption	22.2%	6
Other national provision	3.7%	1

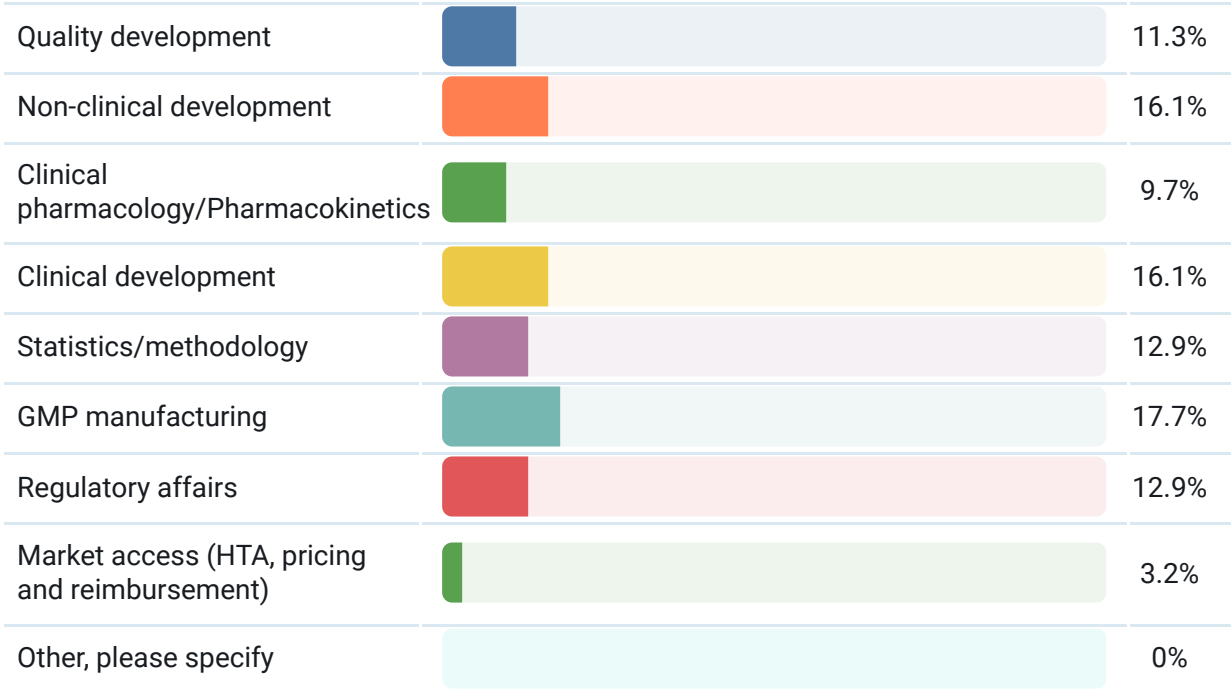
Total answers	27
Unique Respondents	12
Form respondents	95
Respondent Reach	12.6%

Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?



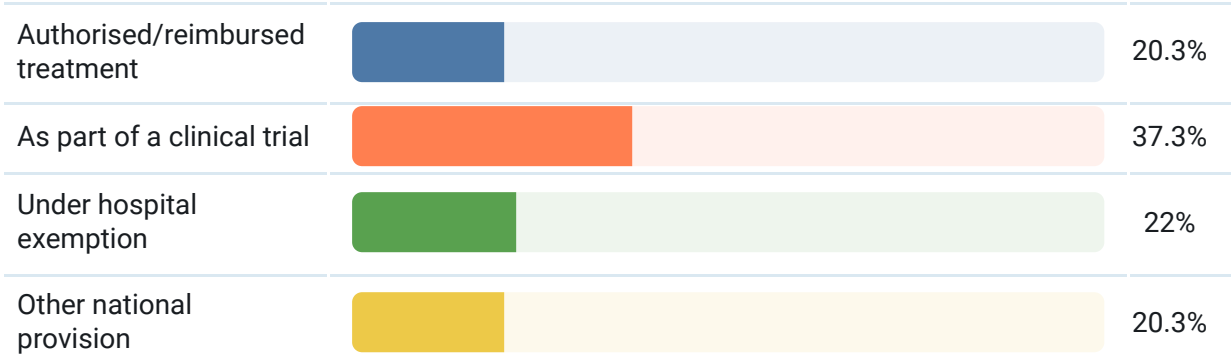
Yes	91.7%	11
No	8.3%	1
Total answers		12
Unique Respondents		12
Form respondents		95
Respondent Reach		12.6%

Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	11.3%	7
Non-clinical development	16.1%	10
Clinical pharmacology/Pharmacokinetics	9.7%	6
Clinical development	16.1%	10
Statistics/methodology	12.9%	8
GMP manufacturing	17.7%	11
Regulatory affairs	12.9%	8
Market access (HTA, pricing and reimbursement)	3.2%	2
Other, please specify	0%	0
Total answers		62
Unique Respondents		11
Form respondents		95
Respondent Reach		11.6%

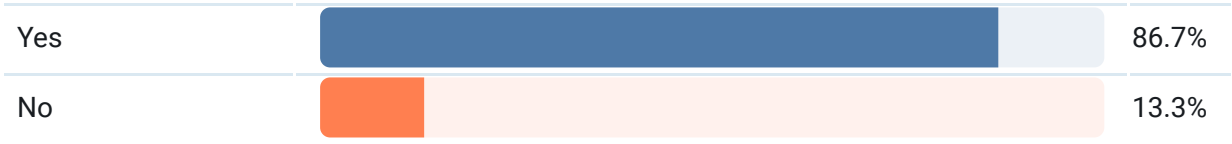
Through which pathway is/are the ATMP(s) you develop, manufacture or dispense provided to patients in your centre, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	20.3%	12
As part of a clinical trial	37.3%	22
Under hospital exemption	22%	13
Other national provision	20.3%	12

Total answers	59
Unique Respondents	30
Form respondents	95
Respondent Reach	31.6%

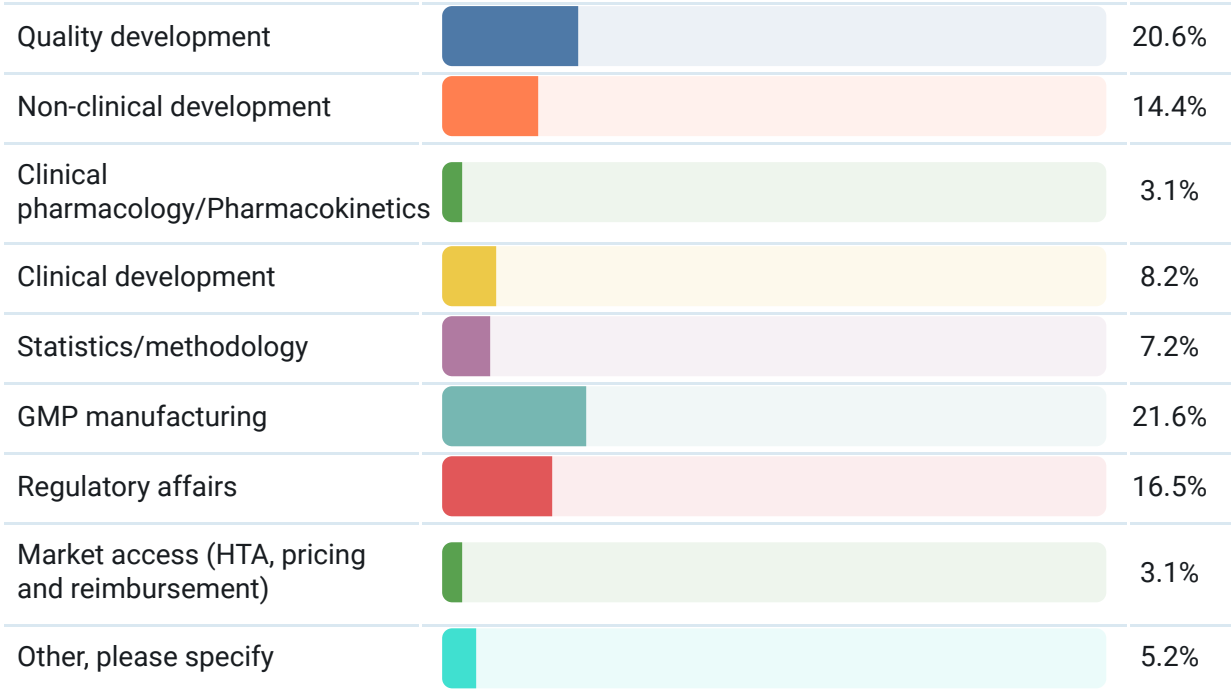
Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?



Yes	86.7%	26
No	13.3%	4

Total answers	30
Unique Respondents	30
Form respondents	95
Respondent Reach	31.6%

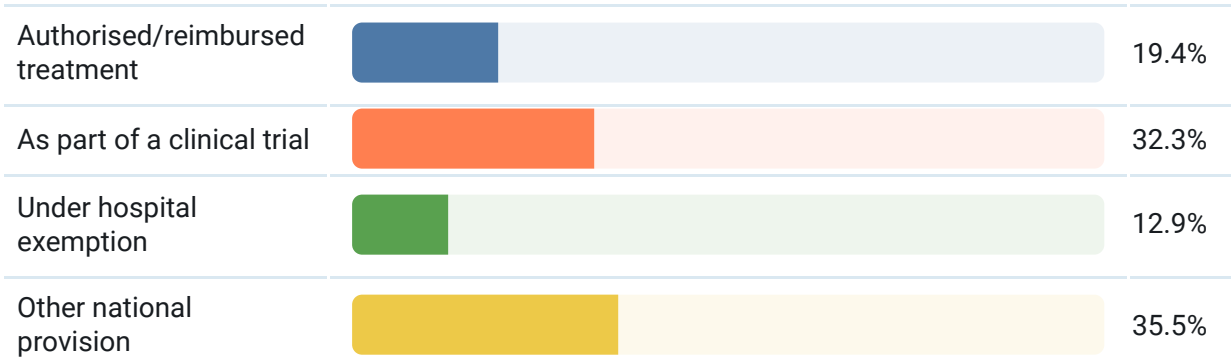
Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	20.6%	20
Non-clinical development	14.4%	14
Clinical pharmacology/Pharmacokinetics	3.1%	3
Clinical development	8.2%	8
Statistics/methodology	7.2%	7
GMP manufacturing	21.6%	21
Regulatory affairs	16.5%	16
Market access (HTA, pricing and reimbursement)	3.1%	3
Other, please specify	5.2%	5

Total answers	97
Unique Respondents	26
Form respondents	95
Respondent Reach	27.4%

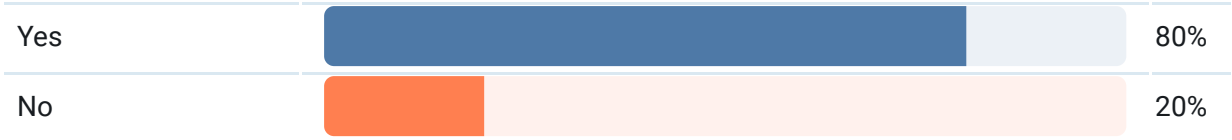
Through which pathway is/are the ATMP(s) you develop, manufacture or dispense provided to patients in your center, region, or country? Please the tick the box, multiple answers possible, and please elaborate your answer (since when / for when it is planned /any background information/links)



Authorised/reimbursed treatment	19.4%	6
As part of a clinical trial	32.3%	10
Under hospital exemption	12.9%	4
Other national provision	35.5%	11

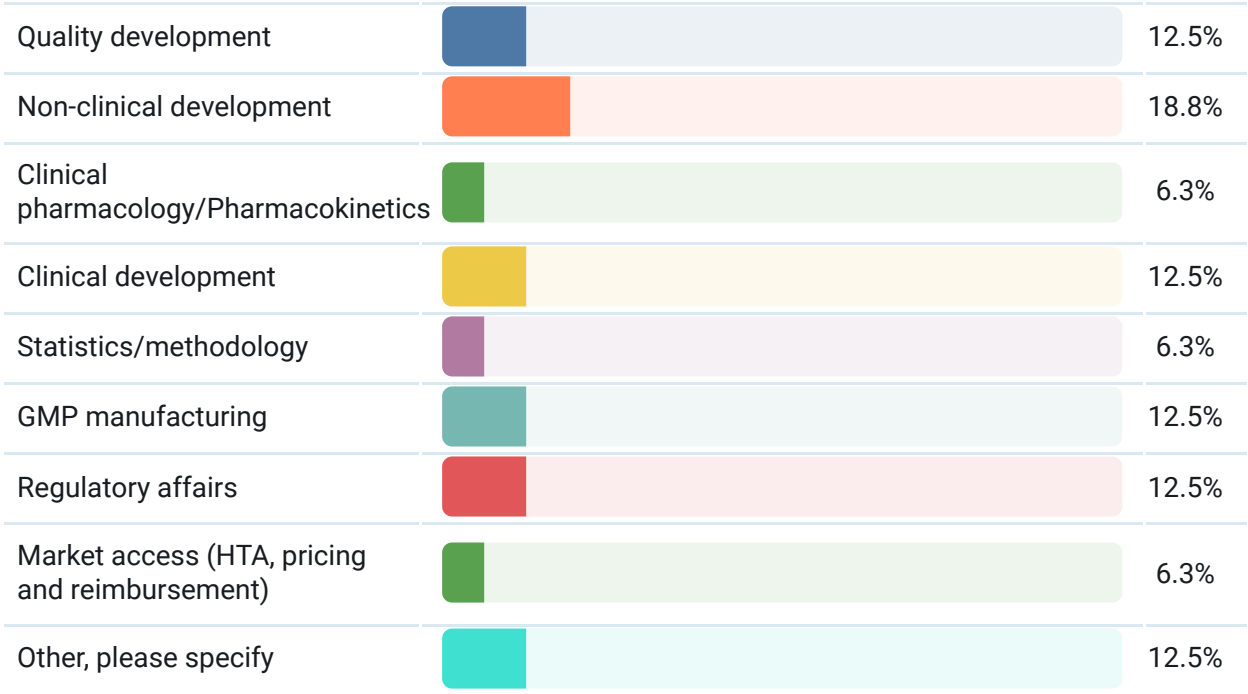
Total answers	31
Unique Respondents	20
Form respondents	95
Respondent Reach	21.1%

Does your organisation have access to cross-functional expertise within your institution or via collaboration/contractual agreement?



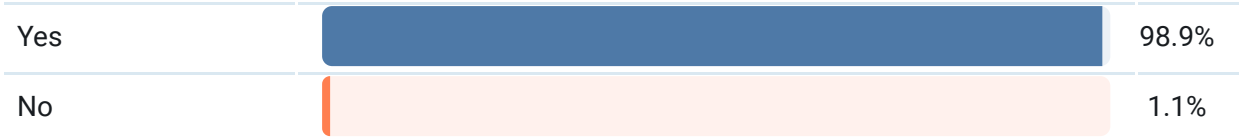
Yes	80%	16
No	20%	4
Total answers		20
Unique Respondents		20
Form respondents		95
Respondent Reach		21.1%

Please indicate to which expertise you have access to (multiple answers possible) and provide additional information if it is in house or external and to which extent it is used:



Quality development	12.5%	2
Non-clinical development	18.8%	3
Clinical pharmacology/Pharmacokinetics	6.3%	1
Clinical development	12.5%	2
Statistics/methodology	6.3%	1
GMP manufacturing	12.5%	2
Regulatory affairs	12.5%	2
Market access (HTA, pricing and reimbursement)	6.3%	1
Other, please specify	12.5%	2
Total answers		16
Unique Respondents		3
Form respondents		95
Respondent Reach		3.2%

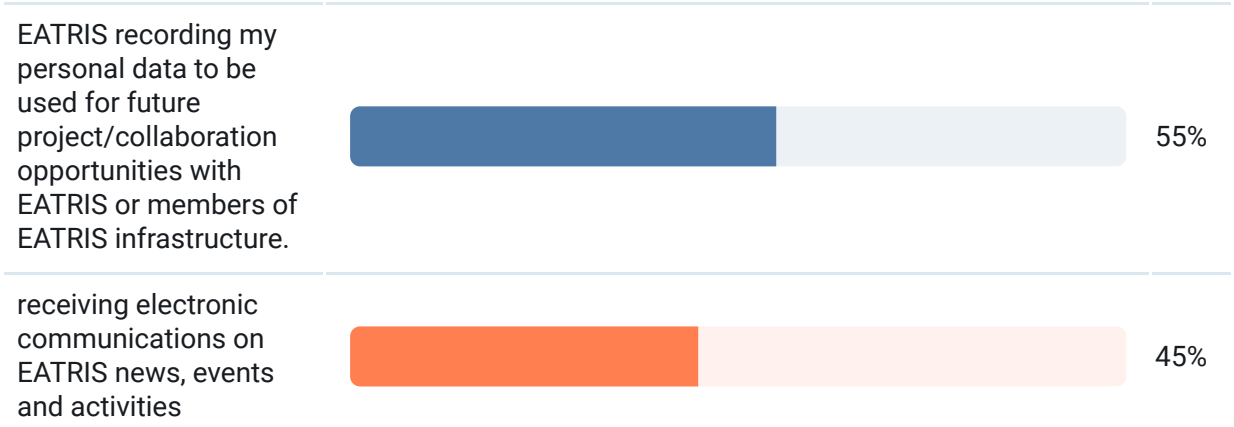
Do you agree to be contacted by EATRIS or the European Medicines Agency about ATMP related activities, studies or events?



Yes	98.9%	94
No	1.1%	1

Total answers	95
Unique Respondents	95
Form respondents	95
Respondent Reach	100%

I agree that my personal data may be processed by EATRIS in accordance with EATRIS Privacy Policy for the purpose of:



EATRIS recording my personal data to be used for future project/collaboration opportunities with EATRIS or members of EATRIS infrastructure.	55%	93
receiving electronic communications on EATRIS news, events and activities	45%	76

Total answers	169
Unique Respondents	93
Form respondents	95
Respondent Reach	97.9%