CHARITÉ

CharitéCentrum für Frauen-, Kinder- und Jugendmedizin mit Perinatalzentrum und Humangenetik

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Study Information

Dear ATMP Expert;

With this information, we would like to inform you about the study and the processing of your personal data and explain your rights. The processing of your data is only permissible for data protection reasons if a legal basis allows it or if you have given your consent. If you have any further questions after reading this information, please contact the person listed below.

JOIN4ATMP survey on ATMPs in Europe

Responsible for data processing is:

Charité – Universitätsmedizin Berlin
Körperschaft des öffentlichen Rechts
Charitéplatz 1
10117 Berlin
Represented by the Chairman of the Board,
Prof. Dr. Heyo K. Kroemer

Executing Authority:

Prof. Annette Künkele-Langer
Charité-Universitätsmedizin Berlin
Klinik für Pädiatrie m.S. Onkologie und Hämatologie
Augustenburger Platz 1
13353 Berlin
Email: annette.kuenkele@charite.de

1) Introduction to JOIN4ATMP:

The EU-funded project JOIN4ATMP brings together all EUHA members with the shared goal of advancing and mitigating risks in ATMP development while ensuring broad access to ATMPs across Europe. This survey plays a crucial role in gaining insights into the requirements for ATMP implementation, as well as identifying potential clinical, regulatory, and economic challenges within your country. By pinpointing these challenges, we aim to propose targeted solutions and craft actionable recommendations for regulators, economic experts, and policymakers to address them effectively. At our website https://join4atmp.eu/ you can yourself inform about the aims, cooperation members and work-pages of our project.

2) Study Guide:

a. Pseudonymous Survey:

In the pseudonymous survey, we collect information about your professional role and expertise in the field of ATMPs. This is followed by five sections focusing on the key topics pre-clinical testing,

GMP, clinical translation, economic frameworks, and stakeholder awareness. You may choose to complete only the section(s) relevant to your expertise. For questions you prefer not to answer, you can select "N/A" or skip to the next question - both options will be recorded as abstentions.

Consent form: Participation in this survey is voluntary. You will only be asked to agree to the study information and participating in the study by clicking the checkbox in the online consent form. A written consent form will not be provided, and by giving your consent, you agree to this. After you confirmed the online consent form and participating in the study by clicking the acknowledgment window, you will then proceed to the questionnaire. You can exit the survey at any time. After submitting the questionnaire at the end, the data will be transmitted to the online database.

Process of pseudonymization of data: All responses will be handled with strict confidentiality in a pseudonymous fashion. If you click on the “submit” button, survey software RedCap will automatically save the answered survey results and automatically assigns a pseudonym (number code) to your answered survey. A list linking the answered survey with email addresses (if you provide your email on voluntary basis) to the respective number codes is stored confidentially at the study center. This list is kept separately at the study center and is subject to technical and organizational measures (see below) to ensure that your personal data cannot be assigned to you by unauthorized persons. In the general information section, you have the option to share personal details or institutional information on a voluntary basis.

The questionnaire contains free-text fields. Please do not enter any data in these free-text fields that could identify you as a person.

Follow-up interview: For maximum impact, we kindly encourage you to provide your email as it would enable us to potentially reach out for an optional follow-up interview (see under b). In this case, and depending on your expertise, the cooperation partner who is working on the relevant work package and requires your expertise will be informed of your willingness to be interviewed.

On our website https://join4atmp.eu/ you can find out which cooperation partners (also listed below) are working on which parts of the project. We will contact you directly and let you know which of the cooperation partners would like to contact you with questions and ask for your consent. It may be the case that several cooperation partners are interested in your expertise. In this case, one cooperation partner will conduct the interview on behalf or with one or more cooperation partner together. We will inform you in advance and will ask for your consent.

b. Optional Interview

As second part of this study, we would like to conduct online interviews via Microsoft Teams including video or phone with selected/volunteered participants to gain deeper insights into the topic. Participation in these interviews is voluntary and will only take place with your explicit consent.

Consent form: Before the interview begins, we will ask for your written consent to the recording and transcription. You have the right to withdraw your consent at any time. In this case, the recordings and transcriptions will be deleted immediately.

Identifiable data: The interview is conducted without pseudonymization so that biometric data (such as face and/or voice) is recorded. The following information explains how image and sound recordings are processed and protected:

Capture of image (video) and/or sound recordings:

During the interview, video and/or audio recordings are made in which face and/or voice are recognizable. If you do not wish that your face is recognizable, please switch off your camera.

We will only collect data in the form of audio recordings during online interviews. These audio files, in which your voice is stored as an identifying feature, are transcribed into text in a pseudonymized form by a commissioned company in a timely manner. After transcription, the audio file will be stored for up to two (2) years and then securely deleted in accordance with data protection regulations, and only the transcription will be stored and used for further research.

Pseudonymization of the transcription: The transcription will be pseudonymized by exchanging the names of the interviewees and any name of a natural person mentioned during the interview with pseudonym codes.

Your identifiable data, the transcription in pseudonymized and non-pseudonymized form will be stored separately at the study center and subject to technical and organizational measures (see below) to ensure that your identifiable data and the transcription cannot be accessed by an unauthorized person.

Use of data from survey and interview: The data collected will be used exclusively for the purposes of the research project and will not be passed on to third parties unless this is required by law. Any published results will be presented as generalized findings and in anonymized form. Should we wish to directly cite any of your responses, we will contact you in advance to request your explicit consent.

3) Purpose of Data Processing

Your data will be processed for the fulfillment of the purposes listed below based on the legal grounds specified therein:

Collection of your opinion:	To understand your satisfaction, needs and recommendations regarding ATMP development.
Research and analysis:	For scientific analyses of hurdles and regulations of ATMP development in the EU.
Improvement of processes:	By evaluating your responses to optimize processes around ATMP development and implementation.
Contacting:	To reach out to you for a follow-up online interview (if you voluntarily provide your contact details).
Online Interview:	The interview aims to collect detailed information and personal assessments on the topics covered in the questionnaire. Your responses will help us deepen the study results and better understand specific issues.

The legal basis for processing your personal data is Art. 6(1)(a) GDPR in conjunction with your consent to the study.

4) Data categories

For the fulfillment of the aforementioned purposes, we process the following categories of data:

Basic master data:	Email (on voluntary basis)
Extended master data:	Name of your institution, your profession, your field of expertise (on voluntary basis)
Recordings	With your consent, the optional interview will be recorded. The recording allows us to accurately capture your responses and analyze them later. The recording will be treated confidentially and used exclusively for the purposes of this study.
Transcription of the Recordings:	The recorded interviews will be transcribed to create a written version of your responses. These transcriptions will be pseudonymized to protect your identity. The transcripts will also be treated confidentially and used only for analysis within the framework of this study.

5) Recipients or categories of recipients of personal data

Your data will be shared in a pseudonymous fashion with the recipients or groups of recipients listed below, (depending on your consent provided):

Recipients within the organization:

- Join4ATMP project team at Charité-Universitätsmedizin Berlin

Cooperation partners:

- Universita Vita-Salute San Raffaele [UNISR], Via Olgettina 58, 20132, Milano, IT
- Aarhus Universitetshospital [AUH], Palle Juul-Jensens Boulevard 99, 8200, Aarhus, DK
- Assistance Publique Hopitaux De Paris [APHP], 55 Boulevard Diderot, 75012, Paris, FR
- Erasmus University Medical Center Rotterdam [ErasmusMC], Department of Internalmedical Oncology Dr Molewaterplein 40, 3015 Gd, Rotterdam, NL
- Karolinska University Hospital [KUH], Hantverkargatan 45, 104 22 Se-171 76, Stockholm, Sehantverkargatan 45, 104 22, Stockholm, SE
- Katholieke Universiteit Leuven [UZL], Oude Markt 13, 3000, Leuven, BE
- Medizinische Universität Wien [MUV], Spitalgasse 23, 1090, Wien, AT
- Fundacio Privada Institut D'Investigacio Oncologica De Vall-Hebron (VHIO) - Calle Nazaret 115-117, 08035, Barcelona, ES
- European Research and Project Office Gmbh [EURICE], Heinrich-Hertz-Allee 1, 66386 St Ingbert, DE
- Rare Diseases Europe [EURORDIS], Rue Didot 96, 75014, Paris, FR
- Fondazione Telethon ETS [FTELE], Via Varese 16/B, 00185, Roma, IT
- Fraunhofer Gesellschaft zur Förderung der Angewandten Forschung Ev [FHOFER], Hansastrasse 27C, 80686, Munchen, DE
- Universitätsklinikum Würzburg - Klinikum der Bayerischen Julius-Maximilians-Universität [UKW], Josef-Schneider-Strasse 2, 97080, Wurzburg, DE

6) Transfer of Personal Data to a Third Country

It is not planned to transfer your personal data to a third country outside the European Union and the European Economic Area.

7) Storage and Protection of Data

Data is stored securely and protected against unauthorized access. Appropriate technical and organizational measures are taken to ensure the security of the data:

Technical measures: Encryption of data, access controls, security software, secure storage.

Organizational measures: Employee training, confidentiality agreements, logging of access, data protection officer.

8) Duration of Data Storage:

We are obligated to follow the rules of good scientific practice and provide proof for a period of 10 years that the published data can be traced back to the original data. For this purpose, we store both your identifying and pseudonymized data at the study center. These data can be linked via a separately stored re-identification list. This list is kept available for audits by review committees or scientific journals. Pseudonymized data are further stored at a long-term archive under GPDR, such as Zenodo, a general open access repository operated by CERN allowing researchers to store and cite various digital data such as research papers, research datasets, software, and reports.

9) Risks of Data Processing and Security Measures

There are confidentiality risks associated with every collection, storage, use, and transmission of data (e.g., the possibility of identifying the individual concerned). These risks cannot be completely eliminated and increase as more data can be linked together. The initiator of the study assures you that everything technically possible will be done to protect your privacy and that data will only be shared with cooperation partners that have an appropriate data protection concept. There are no medical risks associated with data processing.

10) Publication:

Scientific publications of the results will be presented in a form that does not allow any direct identification of your person.

11) Rights of the Data Subjects and Contact

You have the following rights in relation to the processing of your data:

Right to withdraw consent, Art. 7 GDPR
You may withdraw your consent for the processing of collected data at any time. In the event of withdrawal, the responsible parties will promptly review the extent to which the stored data are still necessary. Any data no longer required will be deleted immediately, provided no legal and/or regulatory documentation or reporting obligations prevent this. Please note that data processing carried out prior to the withdrawal remains lawful.
If you wish to exercise your right to withdraw your consent, please contact the executing authority mentioned above.

Right to object to data processing, Art. 21 GDPR
If we process your data based on the legal grounds of Art. 6(1)(e) or legitimate interest Art. 6(1)(f) GDPR, you have the right to object.

Right to access, Art. 15 GDPR
You have the right to obtain information about the personal data stored concerning you.

Right to rectification, Art. 16 GDPR
If you find that incorrect data about you is being processed, you may request rectification. Incomplete data must be completed in accordance with the purpose of processing.

Right to erasure, Art. 17 GDPR
You have the right to request the deletion of your data if certain deletion reasons apply. This is especially the case if the data is no longer necessary for the purpose for which it was originally collected or processed.

Right to restriction of processing, Art. 18 GDPR
You have the right to restrict the processing of your data. This means that your data will not be deleted, but marked to limit further processing or use.

Data portability, Art. 20 GDPR
Personal data provided by you can be made available to you in a commonly used, structured format, if technically feasible.

Contact person:
To exercise the aforementioned rights, please first contact the executing entity using the contact details provided above.
For questions regarding data processing and compliance with data protection requirements, you may also contact the following data protection officers:

Data Protection Officer of the Study:
Behördliche Datenschutzbeauftragte der Charité
Charitéplatz 1, 10117 Berlin
Tel.: +49 (0)30 450 580016
datenschutzbeauftragte@charite.de

Right to lodge a complaint with a supervisory authority:
You also have the right to lodge a complaint with a data protection supervisory authority. If you have concerns about the handling of your personal data, you can contact the following authorities:

Data Protection Supervisory Authority:
Berliner Beauftragte für Datenschutz und Informationsfreiheit
Alt-Moabit 59-61
10555 Berlin
E-mail: mailbox@datenschutz-berlin.de
Phone: +49 30 13889-0
Fax: +49 30 2155050