EP PerMed
European Partnership
for **Personalised Medicine**

Task 5.5 – Engagement and collaboration with key European research and innovation infrastructures

Returning biobank data to participants: Closing the loop

A joint session co-organised with BBMRI-ERIC during the Europe Biobank Week 2026 in Prague.

01.07.2026

TLS & BBMRI

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 101137129.

EP PerMed
European Partnership
for Personalised Medicine

Technical References

Project Acronym	EP PerMed
Project Title	European Partnership for Personalised Medicine
Grant Agreement No.	101137129
Work Package No.	WP5 – International, Transnational, Interregional and Overarching Cooperation
Lead Beneficiary	TLS

List of abbreviations

BBMRI-ERIC	**Biobanking and BioMolecular Resources Research Infrastructure - European Research Infrastructure Consortium**
EP PerMed	**European Partnership for Personalised Medicine**
PM	**Personalised Medicine**
TLS	**Fondazione Toscana Life Sciences**
WP	**Work Package**

DISCLAIMER: Funded by the European Union under the Horizon Europe Framework Programme. Grant Agreement Nº: 101137129. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.

EP PerMed
European Partnership
for Personalised Medicine

Table of contents

1 Background – The importance of the Return of Individual Participants Data and Findings

The return of medically relevant data to participants to research studies (like clinical studies, genomic studies, biobanks) is a growing ethical and regulatory challenge aimed at empowering individuals and building trust in the research process. Historically uncommon, this practice is gaining momentum and aspires to become a standard practice in the future, with the potential to close the loop between people and research, increasing transparency and accountability, and ultimately increasing people's trust in science at large and willingness to share their health data for the development of personalised medicine. Under the EU regulation, participants to clinical trials can ask for their data back, but they are often not aware of this, the process is not straightforward, and, when not carefully executed, it might even compromise the study's results. Currently, this practice may require adaptions of regulatory frameworks, GDPR principles, specific training among healthcare professionals and researchers and balancing clinical studies regulations with the interests of patients and sponsors (the private or public entity that funds the clinical trial). How can we improve the return of this data all over Europe, incorporating participants' perspectives and allowing an easier access for them? How can we best exemplify what has already been done and what is needed from the different observatories?

2 General aim of the session

The joint session *"Returning biobank data to participants: Closing the loop"* is part of the activities planned for the third year of EP PerMed by WP5, under the Task 5.5 "Engagement and collaboration with key European research and innovation infrastructures" (Lead: TLS | Contributors: DLR, ANR, IACS, ISCIII, ZonMw, BBMRI-ERIC). The session was co-organised by TLS and BBMRI-ERIC within the programme of the Europe Biobank Week 2026 (EBW26) in Prague, the Czech Republic. It aimed at being a moment of discussion between stakeholders in the process of returning to participants data coming from genetic/genomic studies and clinical studies. Some examples of successful strategies to address this topic are already in place in countries all over the world, even though alignment and exchange of experiences is lacking and very much needed to address the ethical, legal, societal, infrastructural aspects underlying it. Furthermore, exchange of experiences at the international level can accelerate the uptake of this practice of research.

Returning data to patients and citizens can become a good practice of research and a powerful tool for people engagement, increasing science and genetic literacy, willingness to share health data, and public trust in science and healthcare systems. These aspects are pivotal for a successful development of personalised medicine and a wider acceptance of genomic-based approaches.

3 Logistics

The session was held on May 20th, 2026, at 14-15.30 (CEST), in the frame of the Europe Biobank Week 2026 (EBW26), which took place on 19-22 May 2026 at the Prague Congress Centre, the Czech Republic. The session was jointly organised by TLS, leader of EP PerMed WP5, and BBMRI-ERIC, organiser of the EBW2026. The session was extremely successful with a full conference room of around 120 participants interacting with speakers through questions during the panel discussion time.

The session saw a great participation from EBW26 attendees, with a full conference room.

4 Speakers

The speakers of the session. From left to right: Minja Pehrsson, Daniela Quaggia, Nikolai Paul Pace, Irene Schlünder, Peggy Manders and Matteo Gentili (chairman). Unfortunately, Johanna Blom could not take part in person.

Speaker	Picture	Title
Johanna Blom Professor in Psychobiology and Paediatric and Behavioral Neuroscience, University of Modena and Reggio Emilia CHAIRWOMAN of the session		
Matteo Gentili Project Coordinator TLS and EP PerMed WP5 Lead CHAIRMAN of the session		

Irene Schlünder Senior Legal Expert, TMF/BBMRI-ERIC		*Regulatory and legal challenges of returning data to patients*
Minja Pehrsson Clinical laboratory geneticist, Helsinki Biobank		*Advancing precision medicine through return of biobank results*
Nikolai Paul Pace Associate Professor, University of Malta		*DwarnaBio - the Maltese population biobank and insights from the Genomes of Malta*
Daniela Quaggia Senior Project Manager, Active Citizenship Network-Cittadinanzattiva		*Returning Individual Participant Data in Clinical Trials "by Design": Setting a new standard for research & patients' rights*
Peggy Manders, Head of Radboud Biobank (The Netherlands)		*Biobank participants' choices regarding unsolicited findings and feedback*

5 Overview of the presentations

5.1 Speaker 1: **Irene Schlünder** presented about regulatory and legal challenges of returning data to patients.

The presentation focused on the legal and ethical considerations involved in returning research data to participants. It outlined how different data sources, such as clinical trials, biobanks, cohort studies, and routine healthcare data, are governed by distinct legal frameworks, including the General Data Protection Regulation (GDPR), the Clinical Trials Regulation, national legislation, and the emerging European Health Data Space (EHDS). Irene highlighted participants' rights to be informed, access their data, request data portability, and, in some cases, exercise a right not to know certain findings. The presentation also discussed the challenges associated with returning different types of data, including unsolicited findings, raw research data, laboratory results, imaging data, and omics information. The presentation focused also on practical questions regarding the method of return, the need for medical counselling, data security considerations, and the management of actionable findings.

Irene concluded her talk by emphasizing that many questions remain unresolved regarding the return of participant data. Key questions included:

- What types of information do participants actually want to receive beyond medical data?
- What is the applicable law per data source and data type?
- Cultural differences influencing expectations around participant involvement
- Ethical implications, including the right not to know
- What are the specific risks per data source and data type (data security, medical counselling)?
- Privacy and security requirements for returning results safely. Does the way of returning open up additional concerns, e.g., data security, consent?

The speaker stressed that secure infrastructure, clear governance, and practical implementation models remain underdeveloped and require further discussion.

5.2 Speaker 2: **Minja Pehrsson** presented the Finnish Biobank experience returning genomic findings

Minja presented Finland's national experience with returning actionable genomic findings through hospital biobanks.

Key points included:

- Finnish biobanks generated genotyping data from more than 500,000 samples out of which 300,000 samples are from hospital biobanks
- Finnish legislation, Finnish Biobank Act, allows individuals to request health-related information derived from their biobank samples
- Approximately 68% of donors indicated willingness to receive important health findings

The presentation was mainly focused on the Genome Health Project. Other projects were only shortly mentioned: Rare3K: Accelerate rare disease diagnostics, using systematic clinical data analysis combined with genetic testing of biobank samples to identify previously undiagnosed individuals with rare conditions, who can be directed to appropriate care pathways and iCAN: Support personalised treatment, which integrates tumour molecular profiling from biobank samples into oncology decision-making to support precision medicine and more refined cancer treatment strategies.

Genome Health Project focused on conducting large-scale opportunistic screening for hereditary cancer risk genes. Approximately 200,000 donors were screened for BRCA1, BRCA2, and PALB2 variants. They identified 712 confirmed pathogenic variant carriers and found that two-thirds of carriers were previously undiagnosed.

The return process included:

- Genetic variants are internally validated in a diagnostic laboratory prior to disclosure
- Sample donors who had consented to receive findings significant to their health are contacted with a general notification letter stating that genomic data has been produced from their sample, from which risk information can be analysed
- Sample donors are directed to MyBiobank-portal where additional information is provided and an approval to receive genetic results can be given

- Preliminary results are disclosed by phone by a healthcare professional with training in genetic counselling
- Biobank donors are remitted to regional clinical genetics departments for result confirmation from a diagnostic blood sample followed by genetic counselling

Findings showed:

- 50–70% of contacted participants chose to receive genetic results
- Donors generally expected relevant findings to be returned
- No persistent anxiety was observed among participants receiving genetic results
- Positive participant feedback suggested strong support for expanded screening

Minja concluded that biobank-based opportunistic screening can be clinically beneficial, scalable, and cost-effective. It is EHDS aligned and very positively received by donors. Currently they are expanding the screening of return of results from hereditary cancerous findings to other disease areas as well.

5.3 Speaker 3: **Nikolai Paul Pace** presented the DwarnaBio – the Maltese population biobank and insights from the Genomes of Malta

Nikolai introduced Malta's national population biobank initiative, DwarnaBio, Malta's national population biobank initiative led by the University of Malta. It described how the programme has been designed to support large-scale genomic and health research through a harmonised infrastructure that incorporates dynamic participant consent, multi-omics analyses, health-record linkage, longitudinal follow-up, and the return of clinically actionable genetic findings.

The presentation also highlighted the associated MALGENPOP project, which aims to establish a FAIR-compliant Maltese reference genome and genomic data portal. In addition, it outlined current and planned research activities, including studies of rare genetic diseases, polygenic risk scores, pharmacogenomics, and population-specific genetic variation. Overall, the presentation emphasised DwarnaBio's role in strengthening Malta's research capacity, enabling national and international collaborations, and supporting the future implementation of precision medicine and genomic healthcare.

The presenter concluded that implementation of the MALGENPOP project requires not only technical infrastructure but also social, ethical, and clinical readiness.

5.4 Joint Presentation by Johanna Blom and Daniela Quaggia: Returning Individual Participant Data in Clinical Trials "by Design": Setting a new standard for research & patients' rights

5.5 Speaker 4: **Johanna Blom** presented the FACILITATE Framework and Return of Individual Participant Data (ROIPD)

Johanna introduced the FACILITATE project and its Return of Individual Participant Data (ROIPD) framework.

Core messages included:

- Returning participant data should become a standard component of research ecosystems
- Current approaches remain fragmented and inconsistent
- Data should be viewed as shared assets rather than institutionally owned resources

Key principles discussed:

Governance by Design

- Plan return strategies from study inception
- Move away from ad hoc implementation to a structured governance

Proportionality

- Different types of data require different governance approaches
- Proportionality ensures that return strategies are adopted responsibly according to the maturity, capacity and meaning of the entity that returns genetic results to the participants
- Scientific certainty, clinical relevance, and participant vulnerability should all be considered

Two-Layer Data Model

1. Core Clinical Layer

- Regulates information that is clinically validated and interoperable and potentially medically actionable

2. Participant Choice Layer

- Personal, exploratory, or contextual information

This model avoids simplicity and allows us to ask ourselves what level of governance and participant choice is appropriate for every category of information.

Johanna emphasised moving from asking whether return is feasible toward assessing organisational readiness and enabling implementation.

5.6 Speaker 5: **Daniela Quaggia** presented patient-centred Principles for Data Return that were developed in the FACILITATE Project.

Daniela summarised six practical principles developed through the FACILITATE project:

1. Plan it from day one – clearly define in the trial protocol what will be returned, how and when. Design the "return path" in the protocol and keep it until the post-trial.
2. Put participants first – co-design the protocol with representative patient groups and ensure meaningful, consistent involvement.
3. Provide equitable access – offer similar access across sites, countries, and populations, adapting it to the different needs.
4. Be transparent and accountable – make clear who does what, when, and how. Offer participants accessible support channels.
5. Support understanding – use plain language and, when needed, a clinical touchpoint; training should be provided for all stakeholders involved to ensure they are well-prepared.
6. Learn and improve – measure delivery and experience, address gaps, embed lessons learned in future trials, and share both successes and challenges. Encouraging pilots, evaluation, adjustments and scaling to build evidence about what worked, what is sustainable and what should be done as a best practice

The principles were circulated among different patient associations and institutions to endorse them. The response has been very strong. These principles represent a shared need across ecosystems.

Survey findings showed:

- Approximately 93% of participants wanted access to their individual trial results
- Patients viewed access as recognition of their contribution
- Strong support existed among patient organizations for broader implementation

Daniela emphasized that returning results is not simply a courtesy but a mechanism for strengthening trust and participation.

5.7 Speaker 6: **Peggy Manders** presented the Participant Preferences Regarding Unsolicited Findings

The presentation focused on how biobanks should handle unsolicited findings that result from research. Peggy explained the workflow used at Radboud Biobank, where potential unexpected findings are reviewed by an *"Unsolicited findings committee"* before any decision is made about returning them to participants.

A key element was the introduction of a participant consent template, allowing individuals to explicitly choose whether they want feedback on unsolicited findings.

Data collected from biobank collections showed that a large majority of participants (median 91%) give permission to receive such findings and possible feedback from these findings, although the overall response rate from collections was low. The results were mostly based on percentages rather than absolute numbers, and some participant choices were unclear.

The presentation concluded with several discussion points: the need for better digital consent tools (eConsent), the ongoing debate between the *right to know* and the *right not to know*, and the importance of developing a national policy for handling unsolicited findings in biobank research.

5.8 Panel Discussion

The discussion focused on several recurring challenges.

- **Consent and Culture Change**

Participants debated whether current European reforms (e.g., EHDS) will lead to meaningful changes or simply reinforce existing consent-based systems e.g., genomic data in Germany will remain as opt-in option rather adopt the opt-out proposal under EHDS for secondary use.

- **Funding and Resources**

Speakers repeatedly emphasised that return-of-results programs require substantial funding, clinical follow-up resources are often limiting factors, cost-effectiveness evidence is important for sustainability and more studies should show the cost-effectiveness of returning data.

There is a trend, also reflected in EHDS, to establish information portals, as this is another path to returning individual data and research results to the public. There is a common understanding that such portals need a standardisation, even at the EU level. EHDS could be a starting point and might have an effect also at the global level.

- **Participants Request**

Some panellists questioned how strongly individuals actively seek access to their data, while others reported direct requests for personal and actionable findings. The audience also emphasised that participants increasingly want both individual results and broader research outcomes.

- **Quality assurance was identified as essential**

Returning findings requires validated procedures, diagnostic confirmation, genetic counselling, and clear clinical pathways to avoid harm or misinterpretation.

- **Dynamic consent was discussed as a promising but challenging approach**

While it offers flexibility, dynamic consent, and in particular e-consent, becomes difficult to manage when participants change preferences after samples have already been used.

Overall, the panel agreed that returning participant data is becoming more important, and can be instrumental for PM, but significant barriers remain. Governance, funding, infrastructure, clinical capacity, consent models, and ethical implementation all require coordinated solutions. The discussion emphasised that successful return-of-results systems depend not only on technical capability but on sustainable structures that keep participant needs at the centre.