IDEA-FAST

Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

Grant Agreement No. 853981

**WP8 – Data Protection,
Ethics and Legal challenges**

D8.6: Public report on the governance of the IDEA-FAST platform

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1 Abstract

This report, on the governance of the IDEA-FAST Data Management Platform (DMP), is a Deliverable of the IMI research consortium formed to find digital endpoints that provide reliable, objective and sensitive evaluation of fatigue, sleep problems and activities of daily living (ADL) for several immune-mediated inflammatory diseases(IMID) and neurodegenerative diseases (NDD).

The report describes the purpose, governance and development of the DMP, the data management and the data flows from multiple research institutes and datasets that have emerged during the IDEA-FAST project.

The DMP has been developed and expanded during the project by ICL to support the research performed in the context of the IDEA-FAST Project. FAIR principles, informed consent of participants, and patient-centeredness were considered during the process of the DMP development.

2 Abbreviations

ADL	Activities of daily living
AI	Artificial Intelligence, as defined in the Artificial Intelligence Act COM/2021/206 final
CA	Consortium Agreement
COS	Clinical Observational Study
DBC	Data Breach Committee
DMP	Data Management Platform
DOA	IDEA-FAST Description of Action (Annex 2 of the grant agreement)
ELAB	Ethical and Legal Advisory Board
ELSI	Ethical, Legal and Social Implications
EU	European Union
FAIR	Findable, Accessible, Interoperable and Reusable
FS	Feasibility Study
GA	IDEA-FAST Grant Agreement
GDPR	General Data Protection Regulation (EU) 2016/679
ICL	Imperial College of Science and Technology London
IMID	Immune-mediated inflammatory diseases
NDD	Neurodegenerative diseases
PRO	Patient Reported Outcomes

3 Introduction

The IDEA-FAST project aims to find digital endpoints that provide reliable, objective and sensitive evaluation of fatigue, sleep problems and activities of daily living (ADL) for several immune-mediated inflammatory diseases (IMID) and neurodegenerative diseases (NDD). The digital endpoints are identified through remote assessment of fatigue and sleep disturbances using monitoring sensors and mobile or residential technology. The evaluation is done in the context of a Feasibility Study (FS) and a Clinical Observational Study (COS). For both studies, the raw data of the devices are analysed together with other measurements including standardised clinical data and participant self-assessments. The digital technology is provided by consortium partners including research entities and manufacturers.

The research carried out during IDEA-FAST is described in the Description of Action (DoA). The legal arrangements between the funder and the partners in the project and between the partners are described respectively the Grant Agreement (GA) and the Consortium Agreement (CA).

Work package WP8 defines research and related activities to be carried out within the framework of the IDEA-FAST project, more specifically related to ethical aspects, privacy, and the regulatory context of access to raw data, while considering patient-centeredness and the processing of the data canalised and merged by setting up a Data Management Platform (DMP).

The DMP has been developed, expanded and maintained by ICL during the time frame of the IDEA-FAST project. ICL is the "data processor" within the meaning of the General Data Protection Regulation (GDPR).

The data emerged from the clinical research through multiple institutions established in the European Union, Norway and United Kingdom, as "data controllers". The data are analysed by multiple clinical research institutions within the framework of the IDEA-FAST project.

The governance and access to the IDEA-FAST data on the DMP is currently limited to the IDEA-FAST Partners.

An Ethics and Legal Advisory Board (ELAB) has been established for the IDEA-FAST research consortium to mitigate risks, enhance creditability and foster trust by addressing ethical issues, such as data privacy, integrity of research and societal impact throughout the project. The role of the ELAB is to provide advice on the application of ethical aspects and laws, and to give feedback to the Steering Committee. The report of the ELAB is attached as Annex B.

4 IDEA-FAST Data Flows

The DMP serves to manage the data generated by the IDEA-FAST project for regulatory reasons and as a repository for future related research.

The FS was conducted in three European countries (Germany, Netherlands and UK). The FS aimed to evaluate the feasibility and performance of the various digital technologies used to evaluate their feasibility, acceptability and utility, based on Patient Reported Outcomes (PRO) collected with electronic tools integrated in mobile phone applications. The devices and technologies were then compared to select the most appropriate ones for use in the subsequent COS study.

The datasets generated from the FS thus contain data from sensors and other digital technologies as well as standardised clinical and self-assessment data.

The COS was initiated and carried out in ten European countries (Germany, UK, Netherlands, Italy, Portugal, Spain, Austria, Poland, Norway and Republic of Ireland). At the end of the recruitment phase of the COS in August 2025, a total of 1,891 participants had been recruited across various disease cohorts, consisting of:

- 547 Parkinson's Disease
- 462 Inflammatory Bowel Disease
- 147 Huntington's Disease
- 174 Rheumatoid Arthritis
- 172 Systemic Lupus Erythematosus
- 174 Primary Sjögren's Syndrome
- 215 Healthy Volunteers

Data collection from the most recently recruited participants continued until the end of January 2026.

The collected data includes information processed in completed questionnaires, clinical assessments and measurements originating from digital devices used for the study, research and treatment. Assessment of the participants' conditions of fatigue, sleep quality and daytime sleepiness was based on the participants' own assessment and data processed using the devices and smartphone Apps over several use periods of one week each.

Clinical data was collected by University of Cambridge (UCAM), as (joint) controller, in a clinical database and then transmitted to the DMP (hosted by ICL as processor) Data from the devices and smartphone apps was uploaded directly onto the DMP platform (see Figure 1) where it was aggregated with the data collected from the PROs and data from the clinical database under a unique identifier for each participant.

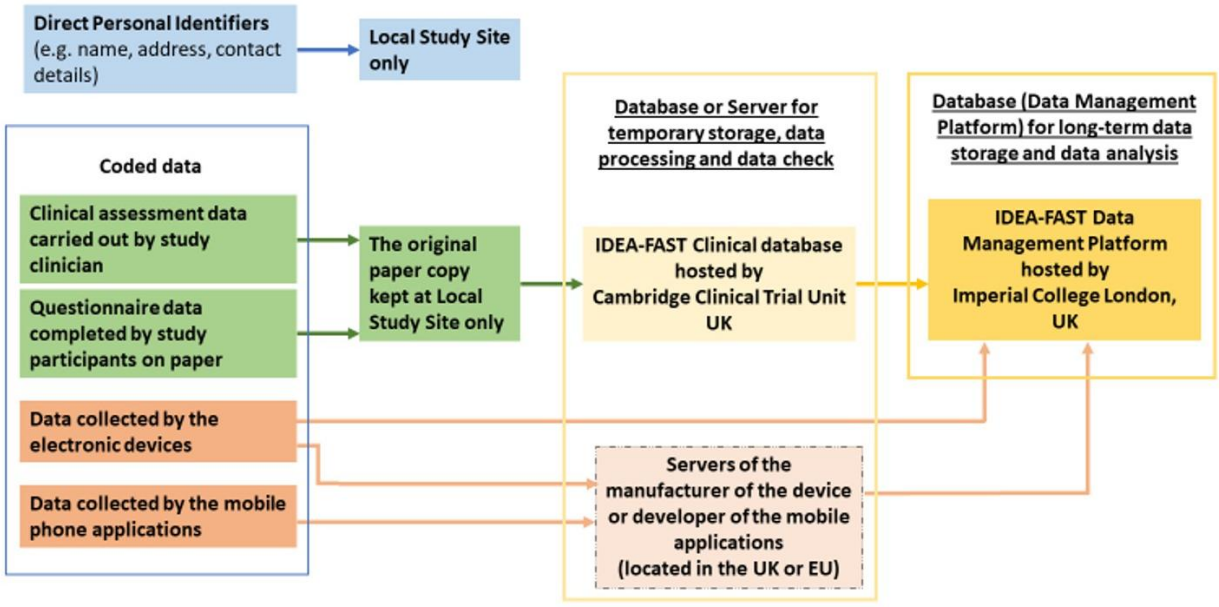

Figure 1: Schematic of IDEA-FAST data flow.

5 DMP structure and developments

Data management strategy and data standards were defined, followed by the development of the DMP for the entire project (WP5), encompassing acquisition strategy based on a clinical data acquisition Standard Operating Procedure (SOP), collection of functional measures and data generated from physiological models, Data Standards strategy, clinical data standards, measurement standards and metadata, FAIR principles, security, GDPR regulations and a strategy for sustainability. The data standards were selected during the IDEA-FAST project, considering clinical knowledge combined with devices and measurements.

The DMP serves multiple purposes including to manage the data generated by the IDEA-FAST project, to support regulatory applications and to act as a repository for future related research. The governance of the DMP is based on the following subsequent steps:

1. Mapping the database use according to legal, ethical and other relevant GDPR issues, and options for 'further use' for research purposes;
2. Mapping the data flows for the research, data protection by design, data security at the various in-between phases and the final DMP;

3. Organising appropriate informed consent for the FS and the COS as well as for the 'further use' of the data within and outside of the research protocol;
4. Establishing the governance of the DMP;
5. Performing a Data Protection Impact Assessment (DPIA) or checking that this has been done for relevant new phases of data processing.

These consequential steps were intended to ensure that the datasets are governed in a balanced way, adhering to the FAIR principles of data reuse within the constraints of data protection to serve its purposes for the public good while at the same time respecting possible intellectual property rights of the contributors.

The platform was created as a hub of curated data, harmonised with clinical information together with the measurements based on a defined data standard. (see Figure 2). The published version of the DMP has been deployed at https://data.ideafast.eu since Q2 2020.

The data managed in the DMP are classified as:

- Raw data, referring to the data captured in the UCAM clinical database and device
- software/applications without processing;
- Integrated data, referring to the datasets processed and standardized clinical and device data integrated into a common model for querying and analysis;
- Metadata, referring to the data describing the IDEA-FAST clinical data and device data (e.g., properties of a dataset or a variable);
- Analytical result files, referring to the data generated from analyses of the above-mentioned datasets.

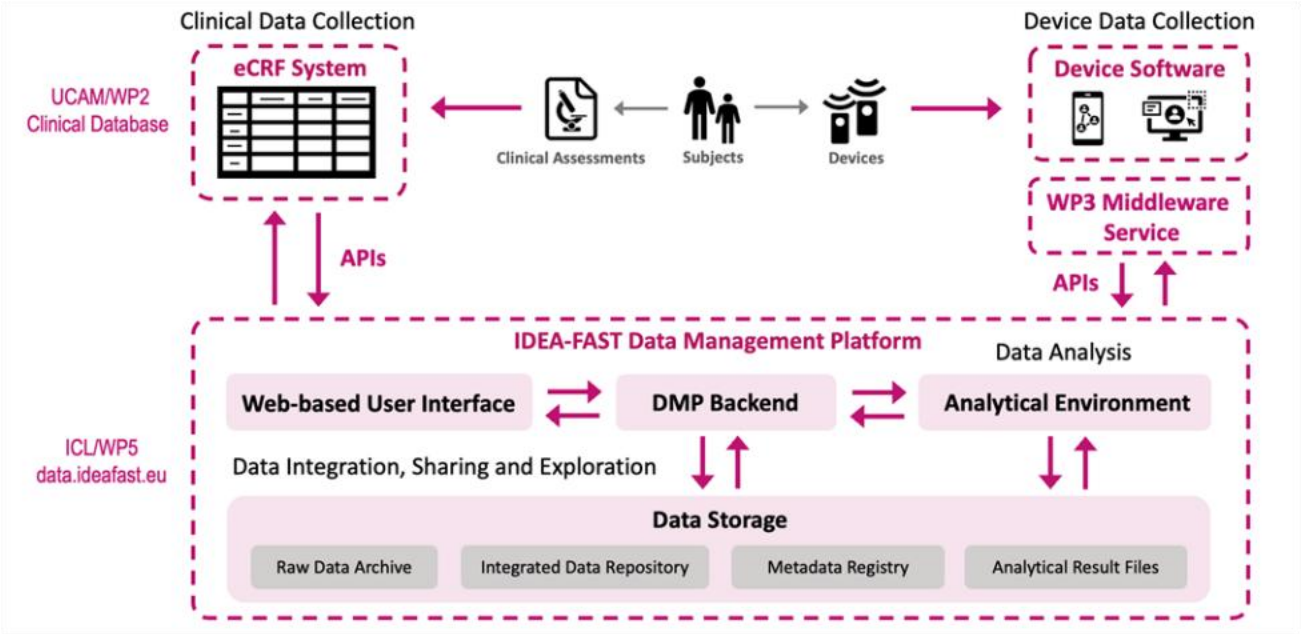

Figure 2: Schematic of the DMP with links to the devices and the clinical database.

6 DMP versions

Three versions of the DMP were developed and released during the IDEA-FAST project and described in the relevant WP5 deliverable (see Table 1).

Table 1: Different versions of the DMP developed during IDEA-FAST.

DMP Version & associated deliverable	Description
DMP V1.0 (D5.6)	DMP Version 1.0, with harmonised clinical and sensor data loaded
DMP V2.0 (D5.7)	DMP Version 2.0, with blockchain-based access control and data provenance system
DMP V3.0 (D5.8)	DMP Version 3.0. This version includes integrated analyses via the Analytical Environment within the DMP. Gaps in managing raw data were addressed by refactoring the DMP backend and introducing TypeScript Remote Procedure Call (tRPC) alongside a new dashboard. The enhancements furthermore aim to simplify complex analytical workflows and improve user experience.

7 DMP certifications

The IDEA-FAST DMP is hosted on servers that are housed in an ISO 9000 certified and ISO 27001 compliant centre including:

- BS EN ISO 9001:2015 – Quality Management
- BS EN ISO 14001:2015 – Environmental Management
- ISO/IEC 27001:2013 – Information Security Management
- BS EN ISO 50001:2011 – Energy Management
- ISO/IEC 20000-1:2011 - Service Management
- ISAE3402 Certification compliance
- PCI DSS v3.2 Compliant
- BREEAM Excellent
- Uptime Institute - Management & Operations.

8 Data Issue and preliminary DBC statute

In March 2025, ICL reported a data loss incident to the IDEA-FAST consortium. At the request of consortium partners, a comprehensive investigation of the data loss was undertaken and an explanation of how the event occurred was given to the partners.

During a meeting between ICL and representatives of WP8, it was established that the loss of data did not result in unauthorised access (by third parties) to the data processed on the platform. However, the analyses of action taken and reporting to the research institutions and members of the consortium led to the conclusion that a description of procedures to be followed in such situations would have been desirable to ensure adequate decision-making within short timeframes.

The procedure has since been described in a protocol template for a Data Breach Committee on a preliminary basis (see Annex A). The IDEA-FAST project (WP8) initiated research on a detailed protocol for handling data issues in the context of international research which will be useful for all EU and IHI projects.

9 Post-project data access

In 2025 discussions were initiated regarding the consequences of the enactment of the European Health Data Space regulations in relation to the datasets developed by consortium members within the IDEA-FAST project.

The options for potential future use and sharing of the IDEA-FAST datasets (repository, open source, joint platform managed by the controllers) were analysed and discussed by the Exploitation & Impact Sub-committee (EIS). These options and findings will be presented in more detail in the final plan for exploitation & sustainability (D9.4).

10 Conclusions

The DMP was developed and established to manage the data generated by the IDEA-FAST project, as a hub of curated data harmonised with clinical information based on a defined data standard for regulatory applications and as a repository for future related research. To this end, the datasets were categorised as either raw data, integrated data, meta-data or analytical result files. Three versions of the DMP have been released. The ELAB has provided its report on the governance of the DMP.

A Data Breach Protocol was drawn up in response to the data loss event during the project.

Discussions about the further use of the data after the end of the project are still ongoing.

Appendix A – Preliminary Data Breach Committee Statute

Preliminary Data Breach Protocol

A Data Breach Committee (DBC) has been established, consisting of:

a) …… (member of the Board)

b) …… (Data Protection Officer/lead privacy, legal)

c) …… (Responsible ICT officer)

d) …… ?

A: In the event of a security incident, the following steps will be taken (1-30 hours):

(for example: stolen laptop, bug, misdirected personal data, hack, lost data, etc.)

i. The DBC is immediately informed by means of ……(?);

ii. .....(member DBC) immediately informs the Board;

iii. The security incident is investigated by A b) and/or the internal or external ICT responsible party;

iv. Any urgent measures are taken;

v. The DBC determines the scope, severity, and consequences;

vi. In case of a possible criminal offense: immediately initiate an official report and file with the authorities in consultation with the board;

vii. Proceed to section B.

B: Is this a data breach?

Are personal data involved/lost, or is unlawful processing possible (i.e. cannot reasonably be ruled out)?

No:

The incident is recorded, measures are taken, the Board will be informed, and the procedure will be closed following a DBC decision.

Yes:

Proceed to section C.

C: Does the security incident involve sensitive personal data* (or for another reason, a significant chance of serious adverse consequences)?

No:

Go back to B(i).

Yes:

i. The incident is recorded, measures are taken, the Board will be informed;

ii. The Data Protection Officer and a delegate of the board will notify the Data Protection Authority (DPA) as soon as possible and within 72 hours (the DPA will send an acknowledgment of receipt);

iii. The file will be kept for at least 7 years;

iv. Improvement processes are initiated following the final DBC meeting;

v. Proceed to section D.

D: Is the data breach likely to have adverse consequences for the privacy of the data subject(s)?**

No (unlikely answer):

i. Record this motivated conclusion;

ii. Report this conclusion to the DPA.

Yes:

i. The DPA and the delegate of the Board notify the responsible authority as soon as possible and within 72 hours (the DPA will send an acknowledgment of receipt), and:

ii. The data subjects are informed in writing about:

a) The data to which the infringement relates;

b) Measures to be taken in terms of e.g. changing passwords;

c) Improvement of the processes initiated;

d) Contact information for questions.

E. Other (post) measures:

i. Organize a final DBC meeting on the procedure and lessons learned and possible improvements;

ii. Register the incident, steps, considerations, reports, notifications, and letters and ensure that the information is kept for at least 7 years.

* Sensitive data includes health information, race, trade union membership, financial status, data that can be misused (identity fraud), usernames, passwords, data that could lead to stigmatization, etc.

** Adverse consequences could include unlawful publication, harm to reputation, identity fraud, or discrimination.

For sensitive data, both the DPA and the affected data subject must generally be notified.

Appendix B – Report of the Ethical and Legal Advisory Board (ELAB)

Abstract

This report provides an overview of the establishment and functionality of the Ethical & Legal Advisory Board (ELAB) within IDEA-FAST. A number of topics for which the ELAB's input was explicitly requested are discussed here in more detail. These topics concerned the invitational workshop, the Data Breach Protocol and Risk Committee and the secondary use of biological samples. The discussions during the various ELAB meetings led to valuable considerations and perspectives. In this process, a careful balance was always maintained between the importance of research and the careful use of data, and the position of vulnerable patients in relation to digitised research.

Ethical and Legal Advisory Board (ELAB)

An Ethical and Legal Advisory Board (ELAB) mitigates risks, enhances creditability and fosters trust by addressing ethical issues, such as data privacy, integrity of research and societal impact throughout the project. The role of the ELAB is to provide independent advice from experts in the field.

The role of the ELAB that has been installed for IDEA-FAST is to provide advice on the application of ethical aspects and laws, and to provide its feedback to the Steering Committee.

The ELAB was supported by the Principal Investigators of WP8, Lygature (Olenka van Ardenne 2024-2026, MLCF (Evert-Ben van Veen) 2020-2023) and TMF (Irene Schluender 2020-2026), as a link between the researchers, patient associations and other parties involved in the project.

Members of the IDEA-FAST ELAB

The ELAB originally consisted of five members. The ELAB membership changed over the course of the project, but there were three members throughout the whole duration, as shown in Table 2.

Table 2: Members of the ELAB.

NAME	AFFILIATIONS	EXPERTISE
Klaus Hoeyer	❖ Professor of Medical Science and Technology Studies, University of Copenhagen	❖ The social and ethical implications of data sourcing
Lynn Rochester	❖ Professor of Human Movement Science, Newcastle University National Institute for Health Research (NIHR) Senior Investigator; ❖ Director, Brain and Movement Research Group.	❖ Gait and mobility in ageing and neurodegeneration (understanding mechanisms of decline, optimized measurement and intervention); ❖ Interest in digital technology to enhance measurement and for novel therapies; ❖ Coordinator of Mobilise-D – IMI Consortium developing real-world digital solutions to measure mobility.
Melanie Goisauf	❖ Senior Scientist at the European Research Infrastructure for Biobanking BBMRI-ERIC, ELSI Services & Research Unit ❖ Lecturer at the Department of Science and Technology Studies at the University of Vienna, and at the Department of Sociology at the University of Malta	❖ Social Scientist (Sociology, Science & Technology Studies, and Gender Studies) ❖ Ethical and social aspects of sharing research and health data ❖ Social implications of genomic research, especially knowledge production and social justice ❖ Artificial intelligence in precision medicine ❖ Stakeholder engagement ❖ Social science research methods.
Past Members:		
Murat Sariya;	❖ Professor of Medical Informatics at Bern University of Applied Sciences;	❖ (Member from 2020-2021)
Herman Nys;	❖ Professor of Medical law at KU Leuven;	❖ (Member from 2020-2021)
Nikolaus Forgó	❖ Professor of IT and IP Law at the University of Vienna	❖ (Member from 2020-2021)

Meetings of the ELAB

Six meetings were held during the project as described in the Table 3. There were mainly held in the first half of the project.

Table 3: Meetings of the ELAB.

Date	Agenda	Discussion/Outcome
16th October 2020	❖ Introduction of Members ❖ Project explanation ❖ The relation of IDEA-FAST ELAB with Mobilise-D ❖ The draft statutes of the ELAB ❖ Discussion on the ELSI (Ethical, Legal, Social Issues) challenges and opportunities of IDEA-FAST and the research it conducts ❖ ELAB Tasks ❖ Ideas and suggestions for invitational workshop on home monitoring to be organized by WP8	❖ Focus ELSI: from GDPR issues to FAIR and "ownership", classical informed consent; ❖ Patient involvement; ❖ Remote monitoring and patient autonomy ❖ IPR issues and FAIR of raw data held by the device makers ❖ Exploring the challenges of home monitoring
8th March 2021	❖ Lecture "Common approaches and frameworks, Digital Health at Open Lab". ❖ Workshop on home monitoring.	❖ The WP3 academic lead (digital devices and technology) presented Frameworks for Participatory &Co-Design in Digital Health and the Learning Healthcare Project. Digital upsides and challenges were discussed. ❖ The workshop aims to reflect, learn from and contribute to ongoing work of IDEA-FAST and to develop guidance on a responsible development and use of digital devices in therapeutic (medicines) development.
3rd February 2022	❖ Briefing of the current state of the project in general ❖ Briefing developments related to the device selection, DMP, FS and COS ❖ The Mobilise-D project	❖ Archiving and access beyond the project ❖ Informed consent document: information on feedback and incidental findings needed ❖ Options for collaboration

17th October 2022	❖ Update on project ❖ WP9 presentation ❖ Discussion on sustainability and FAIR use after project completion ❖ Workshop on home monitoring	❖ Interaction Mobilise-D ❖ EHDS and sustainability ❖ Underserved population – what is being developed should be usable and suitable for all ❖ Workshop goal needs a more specific description
13th June 2023	❖ Update changes to WP8; studies and workshop ❖ Discussion of access to raw data (WP 8.3)	❖ Ethical or philosophical or focus shifting of responsibilities ❖ Raw data versus meta-data, should all sensor data be open and available?
8th January 2026	❖ Draft DMP and ELAB report ❖ Data Breach Protocol (Annex DMP report); ❖ Initiatives WP 8: Guidelines remote monitoring, paper data regulations and Data issues in consortiums; ❖ Further use of samples by commercial parties	❖ Subjects discussed in the ELAB can be described broadly ❖ DBC should have been set up (retrospectively), consider a Risk Committee and document ❖ ELAB Supports a "lessons learned" document ❖ No further discussions ❖ Distinguish between digital data and samples. Samples present sustainability issues. Whether the industry should be able to use the data depends on the purpose

Tasks of the ELAB

During the first meeting, the following tasks for the ELAB were identified:

1) To serve as an internal "helpdesk" and sounding board on project-specific ethical, legal and governance issues as they may arise in the project, complementary to the work to be done in WP8.
2) To provide feedback to WP8 on the governance aspects of the work in IDEA-FAST and other WP8 deliverables pertaining to ethical and legal matters, and particularly in relation to the DMP and the data stored on it.

Secretariat of the ELAB

As discussed in the first ELAB meeting, the secretariat (formed by the PI of Lygature and the PI of TMF) fulfilled a supporting role by regularly keeping the ELAB informed of developments in the project, with a clear ethical and/or legal dimension, to prepare the annual in-person meeting, to act as the contact point for IDEA-FAST partners who want to submit requests to the ELAB and to determine if a request falls within the remit of the ELAB.

ELSI and FAIR principles

During the first ELAB meeting, it was emphasized that it is important to focus on the potential vulnerability of participants throughout the project, in the context of fairness, and in the light of that, to pay attention to stakeholder engagement and population-based reflection. In addition, the balance between legal, ethical, and privacy aspects was discussed. This balance is achieved by carefully weighing the need for data protection and accessibility to support the development of innovative therapies and achieving the maximum benefit for the participant.

It is thus important to find a balance between the FAIR principles and participant privacy.

Invitational workshop

The invitational workshop on "Exploring the challenges of home monitoring from a practical, ethical, legal and societal perspective" was a topic that was regularly raised during the ELAB meetings. Several topics were suggested for the workshop including learning about meaningful patient engagement and how to improve this.

The suggestions of the ELAB contributed to the valuable workshop held on 22nd September 2023, and the development of the Guidelines for patient-centric remote monitoring.

Data breach protocol and Risk Committee

The preliminary data breach protocol document was circulated prior to the ELAB meeting on 8th January 2026. An explanation of this protocol was provided during the meeting. The reason for developing a provisional data breach protocol was a data loss event that was discovered in early 2025. The controller of the data platform assumed that the data loss did not constitute a data breach within the scope of the GDPR. During a discussion between the WP8 lead and the DMP host, it was determined that a provisional protocol is needed for unforeseeable future situations. With this in mind, a provisional document for a Data Breach Committee (DBC) supporting the necessary analysis and steps more effectively and in a timely manner has been developed and shared with the DMP host and the ELAB for clarification and feedback on the situation and the document.

Although the GA, CA and risk assessments already contain a lot of information about data protection, the conclusion of the ELAB discussion was that a multidisciplinary research consortium not only needs a data breach protocol, but also a DBC, that should be set up at the very beginning of the project. This DBC could also be a Risk Committee, with broader responsibilities. In general terms, the aims of this possible Risk Committee may be to monitor risks and reach out to the right people if the unthinkable happens, agree on a set of actions, keep detailed records, and report transparently at an executive level, filtering down to the partner and patient level.

It is important to realise that different jurisdictions within a consortium may complicate the establishment of a generic data breach protocol. Risk management can be navigated within a consortium. A good lesson from our experience with the data loss event is that it would be useful to have a broad set of agreements in the consortium to navigate all these different contexts and

regulations. Patient involvement should also be considered throughout the process of the protocol and data issues.

Secondary use of biological samples

The core of the question discussed in the most recent ELAB meeting was whether biological samples and data obtained in the context of patient treatment and research in a hospital in country X and stored in a biobank in country Y can be made available to profit-making entities for research purposes.

The general principle for analysing data usage is that knowledge will only improve if data is made available for analysis.

The discussion was not only guided by current regulations, but also by the European Health Data Space (EHDS) regulation. In general terms, the EHDS does not distinguish between researchers and commercial entities when giving access to datasets for research.

For both groups, the general principle, that the request must serve the public interest and meet the conditions, applies. However, it is relevant within the context of the question to note that the research may be done within a Secured Processing Environment, as foreseen in the EHDS. This would mean that the data is not transferred to the user.

Secondly, the difference between biobank data and digital data was noted, as samples present sustainability issues. This difference raises several questions including:

1) How do you maintain this dataset?
2) When should the data be made available?
3) Who will you release it to?

These questions have been answered for biobank samples, but not for digital data related to samples. The option of charging direct and indirect costs was considered. While the biobank might be funded, there is no funding for the digital data as there is no digital data biobank facility.

This knowledge might drive the policy for charging costs and determining the price while distinguishing between the data and the infrastructure.

Whether industry should be able to use the samples and/or related data depends on the industry's purpose and specific consent form. The exact purpose of the commercial research will be of essence.

Conclusions

The availability of an external Ethical & Legal Advisory Board for a large consortium dedicated to (remote) research in various countries, entailing data disclosure, analysis and sample storage in multiple jurisdictions, is not only useful but essential.

The ELAB members' considerable expertise contributed to valuable discussions and considerations and support for the IDEA-FAST project.