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

WP1 – Project Coordination & Oversight

D1.1: Project Handbook

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Table of Contents

1 Abstract 3
2 Introduction 3
3 Legal Basis 3
4 Important Contacts 4
5 Consortium Partners 5
6 Management and Governance 6
6.1 Project Coordinator 7
6.2 Project Lead 8
6.3 Project Manager 8
6.4 General Assembly 8
6.5 Steering Committee 9
6.6 Project Coordination Team 10
6.7 Workpackage Leaders 10
6.8 Ethics and Legal Advisory Board (ELAB) 11
6.9 Scientific Advisory Board (SAB) 11
6.10 EFPIA Data Monitoring Board (EDMB) 11
7 Communications 12
7.1 E-mail & E-mail Etiquette 12
7.2 E-mail Reflectors 12
7.3 Sharepoint site 13
8 Project Website and Other Communications 14
9 Financial 14
10 Project Reporting Requirements 15
10.1 Reporting Periods 15
11 Deliverables and Milestones 16
11.1 Approving Deliverables 16
12 File Naming Conventions & Version Control 16
13 Templates 17
14 Conflict Resolution 17
15 Grievance Procedure 18
16 Publication Clearance Procedure 18
17 Procedure for IP Protection and Exploitation 19
18 Minutes of Meetings 19
19 Useful Links 20
20 Conclusions 20

1 Abstract

The IDEA-FAST Project Handbook has two main functions. Firstly, it acts as a reference source for all Consortium members, covering many of the day-to-day activities and providing links to further information where required. Secondly, it aims to standardise various elements of the project e.g. project reports, deliverables, file naming conventions etc. through the use of agreed procedures and templates where relevant.

2 Introduction

The IDEA-FAST Project Handbook has two main functions. Firstly, it acts as a reference source for all Consortium members, covering many of the day-to-day activities and providing links to further information where required. Secondly, it aims to standardise various elements of the project e.g. project reports, deliverables, file naming conventions etc. through the use of agreed procedures and templates where relevant.

This Handbook is a living document and will be updated as necessary, by the project manager, during the project.

For the avoidance of doubt, the Grant Agreement and Consortium Agreement take precedence over this document.

Within this document the beneficiary institutions within IDEA-FAST are referred to as partners. The only exception to this is within the description of committees and boards within the governance structure where partners are described as members of the committee or board.

3 Legal Basis

The project operates within the Innovative Medicines Initiative (IMI) Programme.

The Grant Agreement with the IMI No. 853981 is in operation. The current version of the Grant Agreement is file “Grant Agreement-853981-IDEA-FAST.pdf” and is dated 18/12/2019 on the top of each page. This document can be found in the project SharePoint site at “Documents > Project Files > Grant Agreement”.

A Consortium Agreement has also been signed by all partners. The current version of the Consortium Agreement is the file “IDEA-FAST CONSORTIUM AGREEMENT E-SIGNED.pdf”. This document can be found in the project SharePoint site at “Documents > Project Files > Consortium Agreement”.

4 Important Contacts

Please note that in the publishable version of this deliverable, all contact details will be removed to be compliant with GDPR.

IDEA-FAST Coordinator	IDEA-FAST Deputy Coordinator
Prof Wan-Fai Ng Professor of Rheumatology Translational and Clinical Research Institute Level 3, William Leech Building The Medical School Framlington Place Newcastle upon Tyne NE2 4HH tel: [redacted] email: [redacted]	Prof. Dr. Med. Walter Maetzler Co-Chair of the Neurology Department Klinik für Neurologie UKSH, Campus Kiel Arnold-Heller-Str. 3, Haus D 24105 Kiel, Germany tel: [redacted] email: [redacted]

IDEA-FAST Project Lead	**IDEA-FAST Co-Project Lead**
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IDEA-FAST Newcastle Project Management and Administration

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Victoria Macrae (Clinical Project Manager)
Email: [redacted]

IDEA-FAST IMI Project Officer

Colm Carroll
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TO 56
1049 Brussels
Belgium

Tel. [redacted]
E-mail: [redacted]

Please note that the details of the Project Officer are provided here for information. However, all contact with the Project Officer relating to the project should be through the Coordinator and Project Lead.

5 Consortium Partners

The following table shows the current IDEA-FAST partners. E-mail contact details for all partners can be found on the project SharePoint site at "Documents > Project Files > Contacts and Email Reflectors".

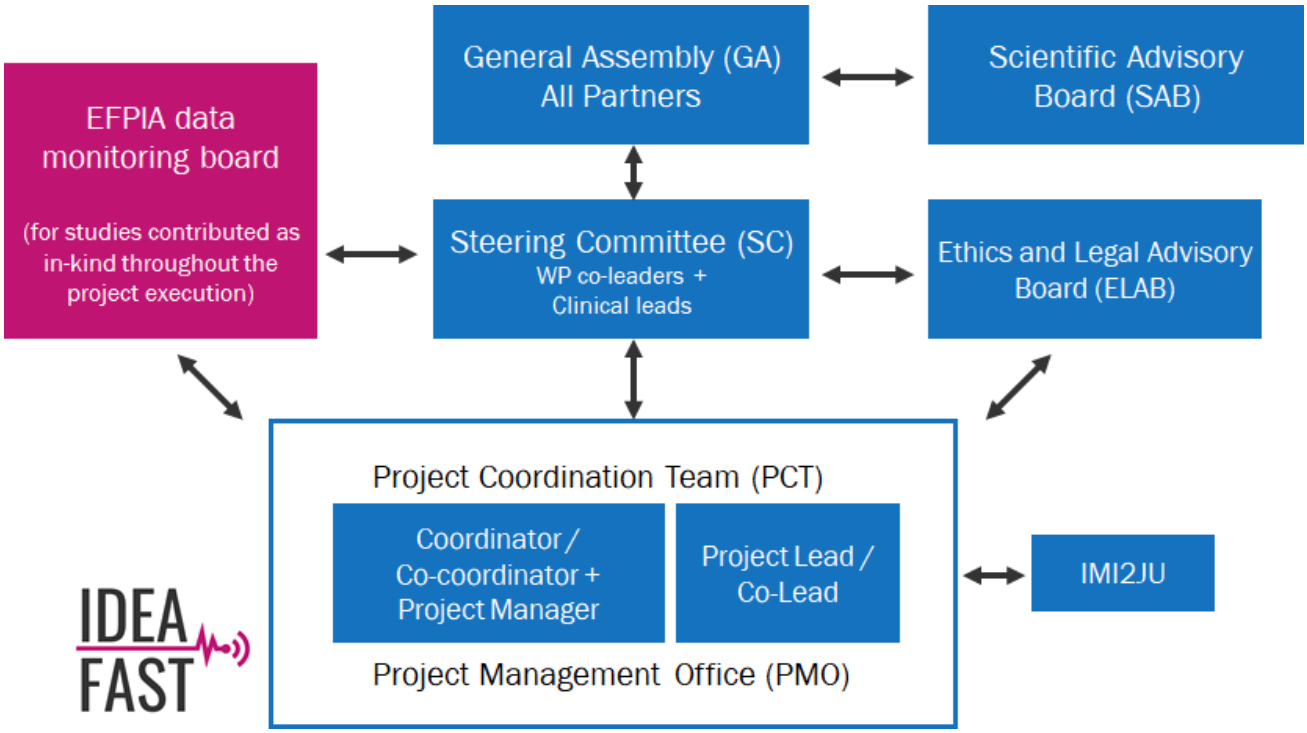
Partici-pant No.	Short Name	Participant Organisation Name	Start	End
1	UNEW	University of Newcastle upon Tyne	0	66
2	UKSH	Universtätsklinikum Schleswig-Holstein (Kiel)	0	66
3	UNIBS	Universita Degli Studi di Brescia	0	66
4	EMC	Erasmus Universitair Medisch Centrum Rotterdam	0	66
5	UGLAS	University of Glasgow	0	66
6	ULIM	University of Limerick	0	66
7	ECRIN	ECRIN European Clinical Research Infrastructure Network	0	66
8	QMUL	Queen Mary University of London	0	66
9	ICL	Imperial College of Science Technology and Medicine	0	66
10	BYTE	Byteflies NV	0	66
11	DREEM	Dreem	0	66

12	UCAM	The Chancellor, Masters and Scholars of the University of Cambridge	0	66
13	LIXOFT	Lixoft SAS	0	66
14	APM	Asociación Parkinson Madrid	0	66
15	MLCF	Stichting MLC Foundation	0	66
16	TMF	TMF – Technologie und Methodenplattform für die Vernetzte Medizinische Forschung e.V.	0	66
17	MBS	Medibiosense Ltd	0	66
18	EMP	empirica Gesellschaft für Kommunikations und Technologieforschung mbH mbH	0	66
19	FC.ID	FCiências.ID – Associação para a Investigação e Desenvolvimento de Ciências	0	66
20	PLUR	Pluribus One S.r.l	0	66
21	IMM	Instituto de Medicina Molecular Joao Lobo Antunes	0	66
22	VTT	VTT Technical Research Centre of Finland Ltd	0	66
23	CCL	Cambridge Cognition Ltd	0	66
24	UAM	Universidad Autonoma de Madrid	0	66
25	IMT	Institut Mines-Télécom	0	66
26	McR	McRoberts BV	0	66
27	GHI	George-Huntington-Institut GmbH	0	66
28	IPIN	Institute of Psychiatry and Neurology	0	66
29	MUI	Medical University of Innsbruck	0	66
30	SUH	Stavanger University Hospital	0	66
31	IXS	iXscient Ltd	0	66
32	EFCCA	European Federation of Crohn's & Ulcerative Colitis Association	0	66
33	LUMC	Leiden University Medical Centre	0	66
34	UoM	University of Manchester	0	66
35	Janssen	Janssen Pharmaceuticals NV	0	66
35a	CHDI	CHDI Foundation (International Partner of Janssen)	0	66
36	TAK	Takeda Pharmaceuticals International AG	0	66
37	ABBV	Abbvie Inc.	0	66
38	AZ	AstraZeneca AB	0	66
39	LILLY	Eli Lilly & Co. Ltd.	0	66
40	PUK	Parkinson’s Disease Society of the United Kingdom	0	66
41	Pfizer	Pfizer Ltd	0	66
42	ROCHE	F. Hoffmann-La Roche AG	0	66
43	SARD	Sanofi Aventis Recherche et Développement	0	66
44	UCB	UCB Biopharma SPRL	0	66
45	BIOGEN	Biogen IDEC Ltd	0	66
46	ORION	Orion OYJ	0	66

6 Management and Governance

Within this section the governance structure and roles and responsibilities of the committees, boards and individuals are described. The text is an abridged version of descriptions within the Consortium Agreement. For avoidance of doubt the text within the Consortium Agreement takes precedence.

The following diagram illustrates the overall project management structures. Members of the various project bodies are listed below.



6.1 Project Coordinator

The Coordinator is Newcastle University (UNEW), represented by Prof Wan-Fai Ng. The Coordinator will be the central point of contact between the partners and the IMI, and will have the following primary responsibilities:

- Overall scientific leadership of the Action in coordination with the Project Lead
- Ensuring, in conjunction with the Project Lead, strong scientific coordination and collaboration between all partners
- Coordinating and managing the Grant Agreement
- Receiving all payments made by the IMI and distributing the IMI funding to partners
- Monitoring overall implementation of the project, in consultation with the Project Lead
- Chairing meetings of the Project Coordination Team (PCT)
- Chairing meetings of the Steering Committee
- Co-chairing meetings of the General Assembly
- Acting upon decisions of the General Assembly and Steering Committee
- Acting as a key contact and intermediary for all scientific and governance issues including external communications; overseeing the technical, financial, technological (innovation impact) and ethical aspects
- Collating and submitting periodic reports to IMI
- Submitting deliverables to IMI
- Financial and contractual administration

6.2 Project Lead

The Project Lead institution is Janssen Pharmaceuticals, represented by Dr Fred Baribaud. The Project Lead will have the following primary responsibilities:

- Overall scientific leadership of the Action in conjunction with the Coordinator
- Ensuring, in conjunction with the Coordinator, strong scientific coordination and collaboration between all partners
- Chairing meetings of the General Assembly
- Co-chairing meetings of the Steering Committee
- Reviewing deliverables and reports before submission by the Coordinator to the IMI
- Ensuring the partners are on track with their obligations as well as with respect to budget, time, deliverables and high scientific quality
- Advising the Coordinator and the various consortium bodies on the allocation and distribution of the IMI financial contribution among partners, in accordance with the Grant Agreement and Consortium Agreement
- Acting as a key contact and intermediary for all scientific and governance issues including external communications, other than the ones entrusted directly to the Coordinator (e.g. with bodies like EFPIA and its internal working groups); overseeing the technical, financial, technological (innovation impact) and ethical aspects
- Coordinating the drafting and negotiation of legal agreements which are needed for implementing the Action, in collaboration with the partners
- Working with the Coordinator and the partners to prepare and negotiate any non-disclosure agreements that may be required

6.3 Project Manager

The Project Manager is iXscient Ltd represented Mr Mike Jackson and Mr David Wenn. The primary responsibilities are:

- Formulating project documentation and templates
- Working with work package leads to develop work plans
- Collating WP reports and overall 6 month project reports
- Reviewing progress in conjunction with Coordinator, Project Lead and Project Executive
- Checking that deliverables are produced according to the work plan
- Advising the relevant bodies on delays, project issues and problems
- Risk Management
- Reviewing use of resources and budgets to advise the Project Executive
- Providing advice and information to consortium partners
- Producing periodic management reports

6.4 General Assembly

The top level of decision making within the consortium is the General Assembly. This will be composed of one representative from each partner organisation and will be chaired by the Project Lead. The Coordinator will act as Co-chair. The General Assembly is responsible for making top-level decisions on the following topics: accession and termination of project partners, project termination, change of Coordinator, matters relating to the strategic direction of the project.

The General Assembly will meet at least every 12 months. Every partner is entitled to submit resolutions to the Committee for consideration.

For a General Assembly meeting to be quorate, at least 75% of its members need to attend, including a representative from each of the Project Lead and the Coordinator. Each partner institution will have one vote in the General Assembly. Decisions will be taken by a double majority, i.e. a majority of at least 51% of the partners receiving IMI funding and a majority of at least 51% of the partners not receiving IMI funding.

The General Assembly is responsible for the overall execution of the Action, alignment across all Work Packages, decision-making and the finding of amicable solutions for any disputes between the Beneficiaries relating to the execution of the Action, where these cannot be resolved within WPs or by the Steering Committee or Project Coordination Team. It will ensure the smooth operation of the Action and guarantee that all efforts are focused towards the Action objectives, deliverables and milestones.

The General Assembly will undertake, and decide on, the following matters, provided such matters and their implementation are in compliance with the terms of the Grant Agreement:

a) supporting the Project Lead and Coordinator in fulfilling their obligations towards the IMI
b) reviewing the progress of the Action
c) deciding on strategic direction, changes to the scope and project direction, proposal to expand or extent the Action, major re-allocation of IMI funding and contribution
d) deciding on principles for effective communication
e) agreeing on procedures and policies in accordance with the Grant Agreement for dissemination of project results
f) agreeing on adequate management procedures, quality standards and quality for the Action
g) agreeing on entries of new partners and departures of existing partners
h) deciding in relation to the service of notice on a terminating partner and the reassignment of that partner's allocated work
i) agreeing on proposals to change direction of the Consortium, including Project Lead and/or Coordinator replacement
j) agreeing on project termination
k) overseeing proper management and administration of the Action and implementation of the provisions contained in the Grant Agreement and in this Consortium Agreement

6.5 Steering Committee

The Steering Committee is responsible for the day to day decision-making and execution of the project, and the initial finding of amicable solutions for any disputes between the partners relating to the execution of the Action. It will review: (i) project progress against objectives, milestones and deliverables; (ii) partner performance; (iii) project plans; and (iv) ethics applications, ensuring no work is undertaken without the appropriate approvals. It will ensure the smooth operation of the Action and guarantee that all efforts are focused towards the project objectives, deliverables and milestones. The Steering Committee will be chaired by the Coordinator, and the Project Lead will act as Co-chair.

The Steering Committee is comprised of the Project Lead, Coordinator and Work Package Leaders (Lead and co-Leads as detailed in section 6.7 below), and the clinical leads (as non-voting members)

Subject to decisions by the General Assembly, the Steering Committee will undertake, and decide on, the following matters, provided such matters and their implementation are in compliance with the terms of the Grant Agreement and Consortium Agreement:

a) monitor progress against objectives and budget
b) ensure effective communication, both externally and between WPs with regard to project progress, best practice and harmonisation and validation across teams using project communication and management tools to ensure operational consistency and efficiency

c) ensure alignment of activities between the WPs and progress towards common goal of success in the project
d) decide on non-major changes to allocated work, budget allocation and risk mitigation plans, and recommend potential changes in project direction for endorsement by the General Assembly.
e) during the project, receive and coordinate all written requests, if required, for access rights to background and/or project results which a partner may wish to make, and forwarding, as appropriate, to the concerned partners
f) mediate conflicts which cannot be handled within or across the Work Packages
g) without limitation to any of the foregoing responsibilities, proper management and administration of the Action and implementation of the provisions contained in the Grant Agreement and Consortium Agreement

In order for a Steering Committee meeting to be quorate, 75% of its members need to attend, including a representative from each of the Project Lead and the Coordinator. Decisions will be taken by simple majority.

6.6 Project Coordination Team

The Project Coordination Team (PCT) consists of the Coordinator, Co-coordinator, Project Lead, Co-lead and Project Manager, with assistance from the Project Management offices of UNEW and Janssen, where relevant. It will meet regularly, mainly via teleconference, in order to discuss day-to-day issues which need to be resolved and, where necessary, referred to the Steering Committee or General Assembly.

6.7 Workpackage Leaders

Each work package has a nominated leader and EFPIA co-lead, as shown in the table below. They are responsible for the deliverables and milestones for that WP. They are also responsible for reporting to the General Assembly and Steering Committee primarily through the Project Manager and they should hold reviews with the WP partners, as required. As they are ultimately responsible for the delivery of the WP, they will be required to implement a project management regime consistent with this responsibility.

Table 1: Work Package Co-Leadership.

WP#	Academic Lead	Industry Lead
WP1 *Coordinator, Co coordinator /Industry Lead Industry co-Lead Project Manager*	Wan-Fai Ng (UNEW) Walter Maetzler (UKSH) David Wenn/Mike Jackson (IXS)	Frédéric Baribaud (Janssen) Virginia Parks (TAK) Manisha Madhoo (TAK) Sofia Jacob (Janssen)
WP2	Walter Maetzler (UKSH)	Virginia Parks (TAK) Manisha Madhoo (TAK)
WP3	Jan Smeddinck (UNEW)	Ioannis Pandis (Janssen)
WP4	Mark van Gils (VTT)	Meenakshi Chatterjee (Janssen) Andrew McCarthy (LILLY)
WP5	Yi-Ke Guo (ICL)	Ioannis Pandis (Janssen)
WP6	Sabine Kläger (ECRIN)	Nadir Ammour (SARD)
WP7	Jérôme Kalifa (LIXOFT)	Stefan Avey (Janssen)
WP8	Evert-Ben van Veen (MLCF)	Virginia Parks (TAK) Manisha Madhoo (TAK)
WP9	Veli Stroetmann (EMP)	David Nobbs (ROCHE)

6.8 Ethics and Legal Advisory Board (ELAB)

The Ethics and Legal Advisory Board (ELAB) is composed of up to five (5) experts with detailed knowledge of ethical policies and/or legal matters relevant to the Project. Experts who make up the ELAB shall represent the various interests involved in the Action. Nominations for membership of the ELAB may be submitted to the Project Coordinating Team by any partner. The Project Coordinating Team shall ensure that the composition of the ELAB is appropriate to provide the guidance required.

The ELAB will be responsible for:

a) reviewing the proper application of the ethical rules by the partners
b) providing advice to the partners, the General Assembly and the Steering Committee on ethical issues
c) providing advice on the compliance with European ethical laws and regulations and with different guidelines, laws and regulations of countries where studies are being performed

The ELAB will meet upon request of the Project Coordinating Team but at least once every 12 months.

6.9 Scientific Advisory Board (SAB)

The SAB is a forum where the project will obtain independent advice from experts in the field. They will review the work of the project and provide feedback to the Steering Committee and General Assembly.

The SAB will consist of up to 8 members external to the consortium with relevant specialist expertise. Nominations for membership of the Scientific Advisory Board may be submitted to the Project Coordinating Team by any Beneficiary. The Project Coordinating Team shall ensure that the composition of the SAB is appropriate to provide the guidance required to achieve Action goals and shall invite nominees to the SAB accordingly. Members of the SAB shall be approved by the General Assembly. The project management team will keep an updated list of SAB members. The SAB will meet at least annually.

6.10 EFPIA Data Monitoring Board (EDMB)

The EDMB is a monitoring board to the Steering Committee. The EDMB will monitor the in-kind contribution of clinical data planned, as well as actual clinical data delivered. Changes to the in-kind contribution of clinical data need to be discussed in the EDMB and endorsed by the Steering Committee.

The EDMB is composed of at least one representative from each EFPIA and/or Associated Partner ("AP") with in-kind contribution of clinical data, as specified in the Grant Agreement Annex 1. The Project Lead shall ensure that the composition of the EDMB is appropriate to provide the guidance required.

The EDMB will be responsible for:

a) Maintaining an overview of the in kind contribution of clinical data planned and delivered
b) providing proposals to the Steering Committee on changes to in-kind contribution of clinical data either requested by the Steering Committee or by an EFPIA/AP partner
c) preparing the (updated) deliverable "EFPIA/AP in-kind contribution of clinical data overview" on a twelve (12) monthly basis.

The EDMB will meet upon request of the Steering Committee but at least once every twelve months during the project.

6.11 Clinical Leads

Clinical leads are not formally part of the project management structure, however they provide a vital role in the delivery of the project by providing guidance regarding their specific disease area ensuring that the work of the project clinically meets the needs of the disease and patient cohorts.

Clinical leads are:

Prof. Wan-Fai Ng - Rheumatoid arthritis, systemic lupus erythematosus, primary Sjögren's syndrome

Prof. Walter Maetzler - Parkinson's disease

Prof. Janneke van der Woude - Inflammatory bowel disease

Dr Ralf Reilmann - Huntington's disease

7 Communications

7.1 E-mail & E-mail Etiquette

When sending e-mails, it should be remembered that many people may be working on a number of different projects and are likely to receive numerous e-mails every day. This can make it difficult to quickly recognise the significance of an e-mail and also to find and segregate related e-mails. In order to ease this problem, IDEA-FAST related e-mails should **always** include in the subject title the short name of the project (i.e. “IDEA-FAST”) followed by a more specific description of the subject.

When sending e-mails with file attachments, please consider the size of the attachment. Very large attachments may not be accepted by the recipient server and even modest size attachments (around several MB) might rapidly cause e-mail quotas to be exceeded, particularly where recipients are away from the office for an extended period. Therefore, consideration should be given to uploading the relevant file to the project SharePoint site instead of attaching it to the e-mail. When replying to an e-mail with a file attachment, please ensure that you delete the attachment unless the attachment is still required (e.g. if the reply is copied to a new group of people).

When replying to an email that has multiple recipients please consider whether you need to just reply to sender or All. If everyone does not need to know your reply, then please limit those you reply to. This will reduce the number of unnecessary emails people receive.

Finally, as a courtesy, please include your contact details on every e-mail that you initiate.

7.2 E-mail Reflectors

To facilitate rapid e-mailing of different sub-groups within the consortium, various e-mail reflectors have been implemented. These are shown in the table below. Please note that in the publishable version of the deliverable all email addresses will be removed.

Reflector name	Members	Address
[redacted]	All project partners (technical)	[redacted]
[redacted]	Partner administration contacts	[redacted]
[redacted]	Core technical team	[redacted]
[redacted]	Clinical leads	[redacted]
[redacted]	Partners working on sensors	[redacted]
[redacted]	Project Coordination Team	[redacted]
[redacted]	Steering Committee	[redacted]
[redacted]	Work package 2	[redacted]
[redacted]	Work package 3	[redacted]
[redacted]	Work package 4	[redacted]
[redacted]	Work package 5	[redacted]
[redacted]	Work package 6	[redacted]
[redacted]	Work package 7	[redacted]
[redacted]	Work package 8	[redacted]
[redacted]	Work package 9	[redacted]
[redacted]	Clinical Knowledge and Insight Task Force	[redacted]
[redacted]	Task Force for Technology Integration	[redacted]
[redacted]	Feasibility Study Implementation Group	[redacted]
[redacted]	EMA regulatory group	[redacted]
[redacted]	EFPIA Data Management Board	[redacted]
[redacted]	Academic Existing Data Sets	[redacted]
[redacted]	UK Institutions (for Brexit-related matters)	[redacted]

Additional e-mail reflectors may be set up on request. Any queries related to these reflectors, requests for additions or for new reflectors should be addressed to the IDEA-FAST Project Manager.

A current list of the members of each e-mail reflector is maintained on the project SharePoint site under “Documents > Project Files > Contacts and Email Reflectors”.

Partners are requested to provide changes required to email reflectors to the Project Manager.

7.3 Sharepoint site

A project SharePoint site has been set up. This will act as a file transfer and archive facility. Access is provided individually to relevant participants with project partner organisations via a link to the SharePoint location.

There are two storage areas under “Documents”:

- **Project Files:** This is a read only area that is the repository of important project documentation, e.g. current versions of the Grant Agreement and Consortium Agreement, formal deliverables, minutes of important meetings, list of e-mail reflectors, etc. Files can only be uploaded to this directory by the UNEW administrative team and IXS.
- **Work Packages:** This is a read / write area where partners can add and edit files as well as create sub-directories for each WP.

Rules for Access and Management

1 – Access to SharePoint will only be granted to persons who have been validated as a member of the project by a partner institution within IDEA-FAST.

2 – All persons registered for SharePoint access must also be on the IDEA-FAST e-mail list. Access may be revoked if they are not on the e-mail list.

3 – All requests for access to SharePoint and registration on the e-mail list go through the Project Manager (IXS).

4 – Only 2 top-level file directories are foreseen “Project Files” and “Work Packages”

5 – The Project Files contains official project documents such as the Consortium and Grant Agreements, Deliverables, contact details etc.

6 – Only iXscient and the Newcastle management team are to add or delete files to the Project Files directory, all other participants have read only access

7 – The “Work Packages” directory is a read / write space for work packages to store and work on files.

8 – Each WP leader can create the file structure needed within their WP sub-directory

9 – No directory structure should be created outside of this

10 – In general, all project participants must be able to view all documents on SharePoint , unless there are exceptional circumstances, e.g. in case of patient confidentiality.

If changes are required to sharepoint access for example if a person within an institution stops working on the project or leaves the organisation, or if an additional person needs access please inform the Project Manager.

Partners are reminded that all information shared within the consortium forms part of the confidentiality agreement as detailed in the Consortium Agreement

8 Project Website and Other Communications

An IDEA-FAST project website has been set up and will be regularly updated (see www.idea-fast.eu). Partners are encouraged to add a link from their own website to the IDEA-FAST home page.

In addition, a Twitter account @ideafastproject and a Linkedin account (https://www.linkedin.com/showcase/idea-fast/) have been created.

Partners are encouraged to link, where possible, institutional accounts to the IDEA-FAST website, twitter and Linkedin accounts.

9 Financial

Details of the individual partner budgets, a breakdown of "Other Direct Costs" and the distribution of EFPIA cash contributions are shown in the Grant Agreement.

10 Project Reporting Requirements

Given the complexity and tight timelines within the project there are requirements to track progress and also collect data for required reports to the IMI.

To track progress internally WP leads will produce a short summary report on a monthly basis which should be sent to the project manager before the individual WP review meetings.

On a six monthly basis, WP leads will produce a Six Monthly Report that details the progress by task in that period. The combination of these will provide a large part of the required periodic technical report to IMI. Templates will be provided for these six monthly reports which should be sent to the Project Manager by the 15th of the month following the end of the period.

Copies of the relevant templates will be available on SharePoint (Documents > Project files > Templates). The templates will be designed to provide the information that is required for the Periodic Report for the IMI. This will simplify the reporting at the end of each period.

The consortium will submit a Periodic Report to the IMI (within 60 days after the end of each reporting period) containing the following:

- Publishable summary
- Project objectives for the period
- Work progress and achievements during the period
- Deliverables and milestones tables
- Details of Project Management activities
- Update on expected project impacts
- Deviations from Annex 1 (if applicable)
- Financial statement (Form C) from each partner receiving IMI contribution including an explanation of use of resources
- Certificate of Financial Statements (CFS) (only in the final period and if required)

In addition, there is a requirement to record other project items such as dissemination and exploitation via an online portal. A template for partners to complete will be circulated to capture this information.

More details on the reporting requirements will be provided at the appropriate time.

10.1 Reporting Periods

The project has five formal reporting periods as follows:

1) 1st November 2019 (Month 1) – 30th April 2021 (Month 18)
2) 1st May 2021 (Month 19) – 30th April 2022 (Month 30)
3) 1st May 2022 (Month 31) – 30th April 2023 (Month 42)
4) 1st May 2023 (Month 43) – 30th April 2024 (Month 54)
5) 1st May 2023 (Month 55) – 30th April 2024 (Month 66)

11 Deliverables and Milestones

Deliverables and milestones should be completed on time. Progress on deliverables or milestones should be reported in the monthly and six monthly WP reports for the period in which they are due. If any deliverables or milestones due in the period are late, an explanation for this MUST be given, as well as any mitigation actions and the anticipated completion date. For deliverables which are not written reports (e.g. prototypes/demonstrators), a brief written summary should nevertheless be produced to accompany the deliverable. A template for the deliverable reports will be produced and will be available on SharePoint (Documents > Project files > Templates).

11.1 Approving Deliverables

To ensure that deliverables are of an appropriate standard, all deliverables will be reviewed by someone who has not been part of the core team writing the deliverable. The prime responsibility of a reviewer is to ensure that the deliverable is complete and of an appropriate standard. Typically, the Project Manager, Coordinator or Project Lead will act as reviewer. Alternatively, the PM will nominate a reviewer. The reviewer will then receive the final draft of the deliverable and provide the partner responsible for the deliverable and the relevant WP leader with a written response by e-mail indicating that the deliverable is ready for release or that elements of the deliverable require further attention giving details. The reviewer may also make minor corrections and format adjustments directly. The reviewer should respond within 5 working days of receiving the draft deliverable. If revisions are required, then the above process is repeated. Once the deliverable has been accepted the completion date will be added to the cover page.

The review process is part of the preparation of the deliverable and WP leaders should take appropriate steps to ensure that the review is completed and the deliverable issued before the due date. The due date is the last day of the month that is specified for the deliverable in the DoA.

The Project Manager will circulate the final deliverable to the consortium and also place a copy on the project SharePoint site. The Coordinator will submit all deliverables to the Commission.

If the WP leader and the reviewer cannot agree to release the document, the matter will be referred to the PCT for a binding decision.

12 File Naming Conventions & Version Control

It is essential that every document circulated to other partners in the consortium includes a version number and date. This will help to avoid the situation where partners are working with old or obsolete versions of documents.

In terms of file names, it is difficult to have a fixed file naming convention which can cover every situation. However, the guidelines below should be followed as much as possible:

1. The filename should be descriptive of the contents and should include the project name e.g. “IDEA-FAST_UNEW_ESMAC_2019.pptx” for a presentation by UNEW at an ESMAC conference in 2019. A presenter name can be used instead of the partner name if desired.
2. Where a document is specific to a particular date, this date should be included in the filename in the form ‘dd-mmm-yy. For example, minutes of a WP4 meeting on 10th February 2020 will be called “10-Feb-2020 IDEA-FAST_WP4 Minutes.docx”.
3. Where a document is likely to be produced in a similar format by various partners, the partner short name should be included in the filename e.g. “IDEA-FAST_Q1 Report_UNEW” for UNEW’s first quarterly report.

4. Where different versions of a document are used, e.g. for deliverables and reports, the version number should be included at the end of the filename. For draft documents, the version number should start at v0.1, and increment in 0.1 steps. Once the document is formally issued, the version should change to v1.0 and then increment in 0.1 steps for minor changes. For a major change, the version will change to v2.0. For example, "IDEA-FAST_D2.1_v0.1.docx" will be used for the first draft version of deliverable D2.1.
5. Only the originating author or owner of a document should increment the version number i.e. when the author has received and implemented all changes to the first draft version of deliverable D2.1, it becomes "IDEA-FAST_D2.1_v0.2.docx".
6. When commenting on a document provided by another partner, the filename should be changed to include the initials of the person or short name of the partner making the changes e.g. "IDEA-FAST_D6.1_v0.1_MJ.docx" if changes to D6.1 have been made by Mike Jackson or "IDEA-FAST_D6.1_v0.1_TAK.docx" if changes have been made by Takeda.
7. When suggesting changes to a document, the use of the track changes feature in Word is recommended to assist the document author/owner.

13 Templates

To enable consistency within internal documentation and project branding for external communication including acknowledgements and disclaimers a suite of templates has been produced. The current list is detailed below. All templates can be found on the SharePoint site at Documents > Project Files > Templates.

Template	**Filename**
Meeting agenda	IDEA-FAST Agenda template.docx
Meeting minutes	IDEA-FAST Meeting Minutes template.docx
Deliverable	IDEA-FAST Deliverable template.docx
Presentation	IDEA-FAST Powerpoint presentation template.docx
Monthly WP report	IDEA-FAST Monthly WP Report_v1.docx
Six Monthly WP report	IDEA-FAST Six Monthly WP Report_v1.docx

14 Conflict Resolution

In the case of a technical, financial or procedural conflict arising among partners, there is a principle of amicable settlement whenever possible at the lowest decision-making body. If there is a dispute within a work package, the WP leader should in the first instance try and resolve the issue, with the aid of the Project Manager if necessary. Only if a resolution is not possible should the matter be raised with the Steering Committee. The Project Manager and the Coordinator should help in the conflict resolution as necessary. Failing such a resolution, the Steering Committee will discuss the issues and vote on a resolution to achieve a binding solution. If necessary, individual partners can seek to convene an extraordinary meeting of the Steering Committee, and all partners are able to put resolutions to that Committee.

15 Grievance Procedure

Should a partner wish to complain about any partner in the Consortium, the first action should be to document, in detail, the grievance, communicating this in private to the Coordinator, Project Lead and the Project Manager. The individual concerned will then be given a right to reply to the complaint, again, in private. The Coordinator and Project Manager will then work to resolve the complaint to the satisfaction of both parties. Partners should refrain from making personal attacks or remarks against any individual.

16 Publication Clearance Procedure

Full details of the publication clearance procedure are given in section 7.5 of the Consortium Agreement. A summary of the procedure is provided below.

During the course of the project many partners will disseminate information about the project through:

- presentations at public events
- posters at public events
- submission of articles for publication in professional and other journals
- other means

There is a duty within the consortium to ensure that information is not disclosed that partners would regard as proprietary, or that they may be using to prepare patent applications. If this type of information inadvertently becomes public, then any subsequent patent applications relying on this information would be invalid. Any information prepared for public dissemination must be made available for review by all partners 30 days in advance of its submission for publication, in order for it to be reviewed it and make comments and changes if necessary.

The partner wishing to publish, present or disclose information about the project must follow the correct procedure as summarised below. This is documented in more detail in section 7.5 of the Consortium Agreement, which takes precedence.

- A partner may not disseminate results generated by another partner or any background or confidential information of such other partner, even if such results, background or confidential information are amalgamated with such partner's results, without the other partner's prior written approval.
- The partner wishing to publish shall forward an abstract and/or draft presentation to the whole consortium. The [redacted] e-mail reflector may be used for this.
- As a general rule, the time-limit for prior notice of any such dissemination activity to be given to the other partners shall be 45 days.
- Following receipt of the aforementioned notification, any of the partners may object to such dissemination activity within 30 days from the date on which they received such notification.
- Should any partner fail to reply within the said period, the disseminating partner may proceed with the dissemination as submitted, to the extent that such dissemination does not include or refer to results or any confidential information of any other partner.

An objection is justified:

a) where protection of the objecting partner's own results or background would be adversely affected by the proposed dissemination; or
b) where the proposed dissemination contains confidential information from the objecting partner; or
c) where other legitimate interests of the objecting partner are harmed.

If such objection is made, the publishing Beneficiary will:

(i) in case of a), extend the review period and delay the proposed dissemination for a period of at least 6 months and up to 9 months to allow the objecting partner to evaluate the patentability and/or to file a patent application for the objecting partner's results or background; and/or otherwise modify the dissemination as requested for scientific or patent reasons;

(ii) in case of b), delay the dissemination until the objecting partner's confidential information is removed from the proposed dissemination;

(iii) in case of c), enter into good faith discussions with the objecting partner on how to address the legitimate interests of the objecting partner, as the case may be, by amending the proposed dissemination. For the avoidance of doubt, the comparison and performance of clinical biomarkers is not regarded as a legitimate interest of an objecting partner.

Please note that all publications MUST acknowledge the funding from the IMI and EFPIA and associated partners. A suitable form of words is "The IDEA-FAST project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No. 853981. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA and associated partners".

17 Procedure for IP Protection and Exploitation

Intellectual Property protection and access rights are detailed in sections 7.4 and 8, respectively, of the Consortium Agreement.

Each partner shall examine the possibility of protecting its results, and, where appropriate, adequately protect them by any means for an appropriate period and within appropriate territorial coverage if:

a) the Results can reasonably be expected to be commercially or industrially exploited, and,

b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection of such results, the partner must consider its own legitimate interests, in particular the commercial interests, and the legitimate interests, in particular the commercial interests, of the other partners. Means of protection may therefore include, but are not limited to, patenting or maintaining the results as confidential know-how.

18 Minutes of Meetings

The keeping of minutes for all project related meetings is extremely important as they are a record of decisions taken and actions required by partners in the project. It is the responsibility of the chair of the meeting to organise the taking of minutes.

Minutes of the General Assembly, Steering Committee and PCT should be stored on SharePoint in the Project Files directory within the meetings sub-directory. Minutes of work package or task force meetings should be stored on SharePoint in the Work Packages directory in an appropriate sub-directory for the WP or task force. A suggested template for minutes is located on SharePoint (Documents/Project Files/Templates). The template has space for attendees, minutes, actions from the meeting and for the meeting agenda to be attached. In general, minutes should be written up and circulated to all members of the meeting for comment and correction within 5 working days of the meeting. The author should set a deadline for response, e.g. 5 working days. After this period, the minutes can be circulated to other relevant partners and uploaded to SharePoint as a permanent record of the meeting. **Minutes of all meetings must also be sent to the Project Manager**. These will then be uploaded on to the IDEA-FAST Project folder.

19 Useful Links

Project Website: www.idea-fast.eu

General information from the IMI including various guidelines is available on the IMI website at www.imi.europa.eu.

General information, guidelines and specific contractual documents are available on the Partner Portal at http://ec.europa.eu/research/partners/portal/desktop/en/home.html.

20 Conclusions

The IDEA-FAST Project Handbook has been written in order to provide a reference source for all Consortium partners, covering many of the day-to-day activities and providing links to further information where required. The Handbook also aims to standardise various elements of the project e.g. project reports, deliverables, file naming conventions etc. through the use of agreed procedures and templates where relevant.

This Handbook is a living document and will be updated as necessary during the project.