Masterclass – how to unlock the potential of data sharing in collaborative projects

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OVERVIEW OF THE PLAYBOOK

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A resource to help you navigate data sharing

- Interactive
- Flexible
- Visual
- Pragmatic
- Solution-oriented
- More than 50 connected resources

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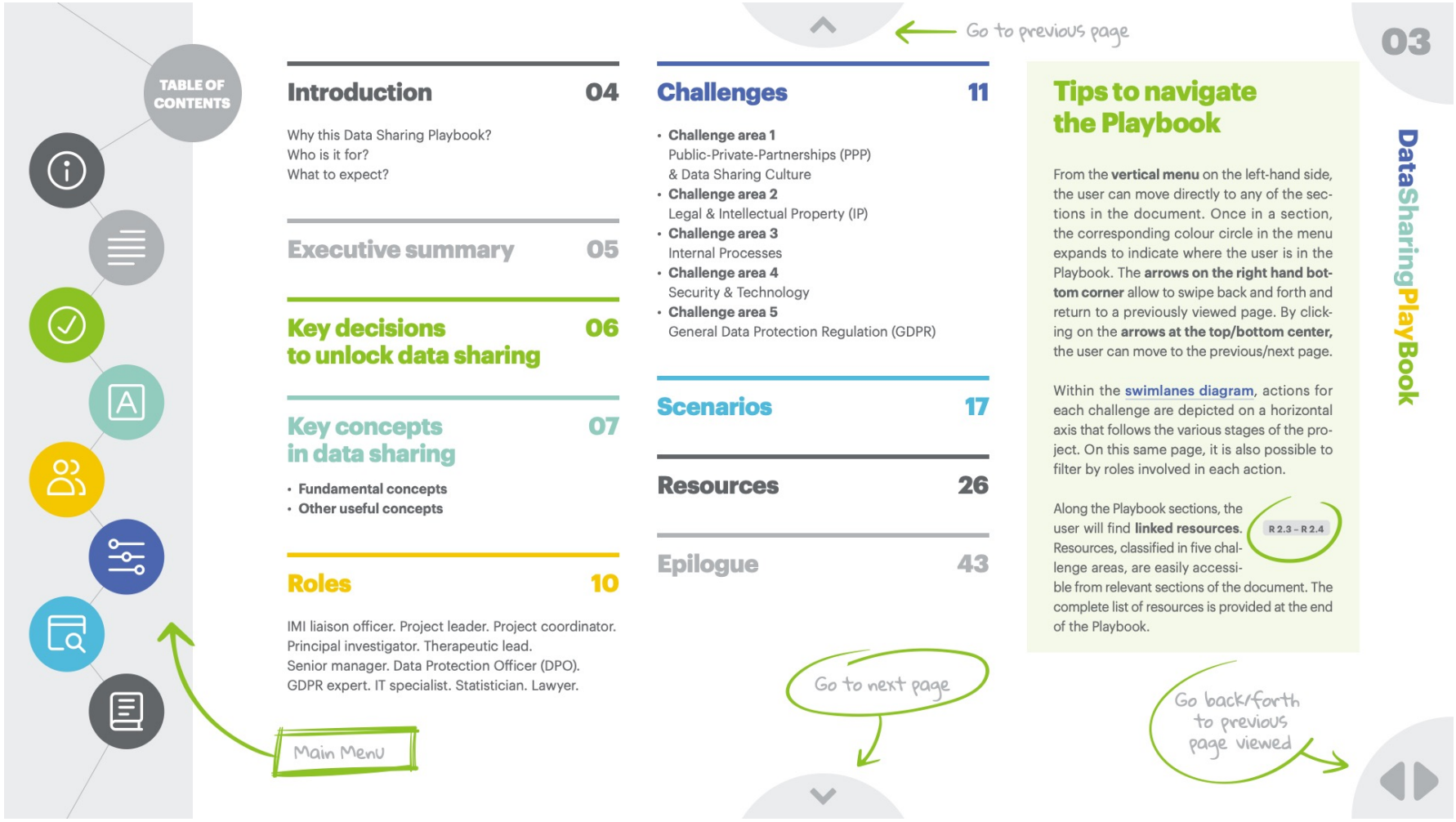
How to navigate this Playbook



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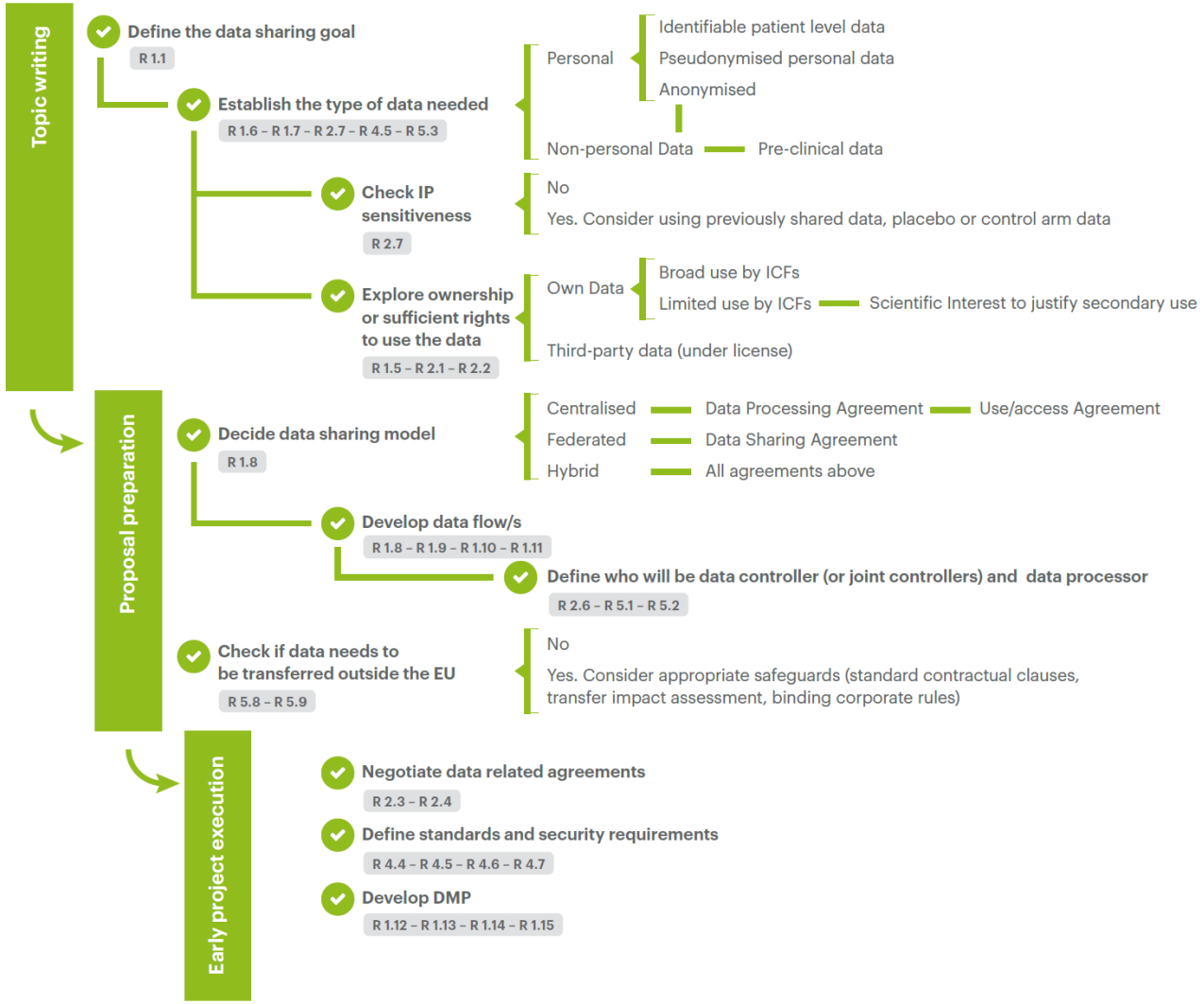
Key decisions to unlock data sharing

This figure represents in a summarised manner key decisions to be taken during the project life cycle regarding data sharing. Links to resources available in the final section of the Playbook are offered next to each checkpoint.



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Roles

IMI/IHI liaison officer

The point of contact within an organisation (e.g., industry partners) for matters related to IMI/IHI projects. This role typically oversees cross-cutting aspects of the IMI/IHI project portfolio within an organisation.

Project leader

This person usually leads the project on the industry side. In charge, together with the project coordinator, of the overall scientific and project leadership.

Project coordinator

In IMI projects, this role leads the project on the public consortium side and is in charge, together with the project leader, of the overall scientific and project leadership. Additionally, this role oversees the grant administration aspects. In IHI this role can also be held by an industry partner.

Principal investigator

This role is responsible for the design and conduct of research (e.g., clinical trials), supervision of staff, producing deliverables, results and research findings. This role is the main contact person for scientific matters regarding a specific project.

Therapeutic lead

Responsible for leading and coordinating the organisation [usually industry] strategy regarding a disease area.

Senior manager/ Academic lead

Manager in a senior-level position who has the authority for planning and directing the work of a team, in a specific scientific area, and in line with strategic objectives and budget. This is a department leader role (or higher) and has responsibility to monitor the work of others and take corrective actions when necessary.

Data Protection Officer (DPO)

The guardian of data protection within an organisation. This individual acts as an independent advocate for the regulated care and use of personal information. This role is responsible for ensuring that an organisation is compliant with the GDPR and other relevant legislation. For some organisations, this role is mandatory by law. The role of a DPO is formally laid out by the EU as part of the GDPR.

GDPR expert

Specialist with a clear understanding of the General Data Protection Regulation (EU) 2016/679, a fundamental regulation in EU law on data protection and privacy in the European Union (EU) and the European Economic Area (EEA).

The description of these roles is indicative, reflecting the skills & expertise deemed necessary to facilitate data sharing.
All the roles are not necessarily involved in a project, depending on the objective of the project and the organization of each partner.

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Involvement of Roles in Data Sharing decisions

- *Several Roles intervene in the process to facilitate data sharing. This swim lanes tool visually identifies who should participate in each data sharing decision or action along the project life cycle.*
- *The main decisions and actions associated with the 5 data sharing challenge areas are described in each swim lane (1- PPP and Data Sharing Processes, 2- Legal/IP, 3- Internal Processes, 4- Security/IT, 5- GDPR).*
- *In the header, the main Roles involved are represented (definitions can be found in the Roles section). The user can click in any of the Roles displayed and the actions in which the Role should participate will be highlighted. By ticking the "Clear selection" button the tool will be cleaned.*

IMI liaison officer | GDPR expert | IT specialist | Therapeutic lead | Senior manager/ Academic Lead | Data Protection Officer (DPO) | Lawyer | Principal investigator | Statistician | Project leader | Project coordinator

	TOPIC WRITING	PROPOSAL PREPARATION	GRANT AGREMENT PHASE	PROJECT EXECUTION
CH1 PPP and Data Sharing Processes	• Outline convincing business case for data sharing • Make an initial selection of potential datasets • Ally with experienced data sharers in the consortium • Train the project leadership team	• Involve staff with previous in-depth IMI experience • Involve the consortium in selection of data sets • Consider outsourcing support activities • Draw initial data flows	• Get guidance from the IMI liaison	• Prepare internal stakeholders organise data flow workshop
CH2 Legal/IP	• Identify type of data needed to address research question • Explore legal/IP limitations of data to be shared (which should be in line with the Access Rghts in the CA)	• Examine if trial data can be shared, rights on 3rd party are adequate and informed consent is sufficient • Involve legal experts	• Map project legal components • Append Template DSA/MTA in CA • Include Mandate to sign DSA	• Confirm understanding of Data Sharing principles in consortium • Set up legal agreements asap • Develop ICF for prospective data collection
CH3 Internal Processes	• Consult internal data sharing organisational policy & processes • Perform risk/reward analysis • Identify datasets internally • Ally with experienced colleagues • Involve internal stakeholders	• Secure senior management approval • Use impact demonstrators from other projects		• Involve all internal stakeholders; be aware of staff turnover • Start data sharing clearance to expedite process • Use internal data release tools
CH4 Security/IT	• Consider security of data needed to address research question • Select auditable standard	• Utlise Common Data Model and/or Platform for Data Sharing • Set IT security requirements • Agree on data anonymisation strategy • Identify solutions to be used for Data Sharing	• Add IT security requirements to CA (e.g. via the Data Management Plan or to be included in a DSA)	• Align IT security review process across EFPIA partners • Agree to data exchange formats (to be included in the Data Management Plan, the DSA/DTA)
CH5 GDPR	• Review Initial use and access	• Check ICF template • Plan if DS outside EAA is needed • Define and agree the roles of controller, joint controller and processor	• Include DPA and/or joint controller agreement template in CA	• Develop DMP in early phase • Conduct DPIA • Organize data flow workshop checking all assumptions made • Introduce SCC for outside EAA sharing

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The challenges

Gary Saunders - EATRIS

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CH1

Public-Private-Partnerships (PPP) & Data Sharing Culture

INTRODUCTION & CONTEXT

It can be difficult to understand PPPs and the specific relationships between stakeholders, which are different and go well beyond the traditional customer-provider relationship. Specifically, this can be a challenge for newcomers to these types of partnerships; it can often be difficult to find agreement, appreciate the drivers for other parties, and both envisage and demonstrate added value to all involved. To demonstrate the value of PPPs it can be very helpful to highlight several parameters from impactful PPPs, for example, regulatory impact, improved endpoints, prediction biomarkers, patient segmentation, technology tracking, and insights gained from analyses of big data.

FREQUENTLY ASKED QUESTIONS

How to best construct IMI/IHI consortia to ensure internal support that enables effective and efficient data sharing?

- Consider strongly the involvement of company experts with PPP experience in proposal drafting.
- Conduct PPP training for novice project leads and coordinators to gain important insights at both the operational and senior levels.
- Create a network(s) of IMI/IHI project leads and coordinators inside and across organisation partners that can share experiences and best practices.
- Keep in mind the sustainability of project outputs.

RESOURCES

1.3 Sharing and reuse of individual participant data from clinical trials: principles and recommendations
1.4 Revolutionizing Medical Data Sharing Using Advanced Privacy-Enhancing Technologies: Technical, Legal, and Ethical Synthesis
1.5 Sharing Is Caring – Data Sharing Initiatives in Healthcare
1.6 Data sharing policy: example of EOSC-Life Data Sharing Policy of the COVID-19 repository
1.7 BigData@Heart - Responsible data sharing in a big data-driven translational research platform: lessons learned
3.5 Involvement of Roles in Data Sharing Decisions

How to best extract, define and ensure added value from PPP?

- Construct a clear and easy-to-apply methodology to assign value to data sharing in order to stimulate the sharing in IMI/IHI projects.
- Report and disseminate impact(s) of previous PPP projects as an exemplar for the present project.

RESOURCES

1.1 The case of data sharing in precompetitive settings
1.2 Status, use and impact of sharing individual participant data from clinical trials: a scoping review

How to best deduce and understand PPP data flow(s) within IMI/IHI projects?

- Create and assess the entire project data flow, including 'who has access to what?' before the project starts.
- Identify the key players so that they assist in the data flow preparation, supported by a consequent workplan.
- If this cannot be done at such an early stage, plan to agree and establish the data flow/s, as part of the DMP.

RESOURCES

1.6 Data sharing policy: example of EOSC-Life Data Sharing Policy of the COVID-19 repository
1.8 Schematic data flows with GDPR roles
1.9 Dataflow overview
1.10 IMI HARMONY Data Flows
1.11 IMI H2O Data Flows

How to best avoid commonly seen pitfalls related to data sharing in PPP?

- Confirm with all involved partners (i.e., in a workshop setting) that they understand and agree with the committed level of data sharing (not only high-level principles but what it means exactly for each partner) as early as possible.
- Ensure that foreseen capacities are clearly described and budgeted.
- Consider procurement of services that are not the core business of any of the partners in the consortium, as these tend to become bottlenecks otherwise.

RESOURCES

1.12 Data Management in EU Collaborative projects (not yet available for HE)
1.13 DMP template Horizon Europe
1.14 DMP IMI H2O Project
1.15 DMP IMI Conception Project
1.16 Data Access Committee

CHALLENGES

CH2 Legal/IP
CH3 Internal Processes
CH4 Security/IT
CH5 GDPR

Legal & Intellectual Property (IP)

INTRODUCTION & CONTEXT

Agreeing on the legal framework and contracts within PPP can be incredibly time-consuming. Although contracts and frameworks are often similar, there is no clear vision on how all legal components/agreements link together. Therefore, establishing agreements across large consortia and accompanied procedural scrutiny are often lengthy processes. Involvement of legal experts with PPP experience (i.e., previous projects) in proposal drafting is often beneficial but due to workload of these seasoned personnel, this is commonly not easy to achieve.

FREQUENTLY ASKED QUESTIONS

How can partners best select which data to share in PPP projects?

- Consider protection of IP in PPP, in particular when compound-related data are involved.
- Check ownership and third-party rights on the data before making any commitments for data sharing.
- Consider sharing data that have already been shared and approved (i.e., in previous PPP and/or with regulatory authorities). A new approval process will likely be needed (due to a different purpose of use for the data), but the fact that it has been shared before may facilitate the ability to share it.
- Assess as early as possible the confirmed ability, in terms of consent and ethical approval, to share data that are planned to be shared.

RESOURCES

1.4 Revolutionizing Medical Data Sharing Using Advanced Privacy-Enhancing Technologies: Technical, Legal, and Ethical Synthesis

1.5 Sharing Is Caring – Data Sharing Initiatives in Healthcare

2.7 How does Pharmaceutical IP work?

How best to check consent agreements for data within large PPP consortia?

- When checking for "informed consent" bear in mind that consent for participation in a trial and consent for access to data (GDPR) are in principle two different things. Clinicians will often, in first instance, think about the former definition.
- Confirm as early as possible that consent agreements and/or licenses allow the sharing of data that are planned to be used in the PPP in order to avoid potentially lengthy delays. Checking of the ICF language can be done by a requlatory attorney, privacy officer or CT manager. If there is a need to adapt the study ICF template with project specific wording (in case of prospective studies performed as part of the project or as in-kind contributions), then the regulatory attorney will always have to be involved.
- Request that all partners in a PPP make available their Informed Consent Forms (ICFs) templates to check the permissibility of intended data usage within the PPP. If ICFs templates cannot be shared, specify what language needs to be included in the ICF to enable use of data for the project. Then each partner can incorporate such additional language in their own templates. In these situations, where the ICF cannot be shared, it is recommendable to contractually capture by way of representations and warranties of the contributor that compliant ICFs are in place, that they allow for implementing project tasks and that state which restrictions are applicable for Research Use. The use restrictions from the ICF can also be formulated in a data intake form for the project, e.g., a Terms of Use (ToU) form.
- Be aware that already existing data sets often have incomplete informed consent in terms of secondary use which may complicate further data sharing considerably.

RESOURCES

2.1 IMI DO-IT Project Informed Consent Forms templated

2.2 German Medicine Informatics Initiative broad consent

How to construct effective legal frameworks in PPP consortia efficiently?

- Ensure every consortium partner legal colleagues are actively involved as soon as possible to facilitate understanding and the sense of collaboration in PPP.
- Construct a clear idea of the data flow/s in the project before the Consortium Agreement (CA) is signed. The data flow will be essential in determining the legal agreements needed in the project. Start with a high-level understanding and define clear milestones/deliverables early in the project to determine the full details.

CH3

Internal Processes

INTRODUCTION & CONTEXT

Unclear internal data release processes and chains of decision-making can often prevent/delay the sharing of data in PPP, leading to long lead times between the decision to share data and actual data sharing.

FREQUENTLY ASKED QUESTIONS:

How to best expediate data sharing within PPP?

- Identify and involve all internal stakeholders as soon as possible in the discussions and ensure their buy-in.
- Assess data sharing in a risk/reward analysis with clear details on the intended data usage(s).
- Consider using demonstrators of impact(s) from other PPP data sharing as helpful and persuasive reference.

RESOURCES

1.1 The case of data sharing in precompetitive settings
3.4 Frontloading data sharing decisions in IMI/IHI projects: advantages and limitations
3.5 Involvement of Roles in Data Sharing Decisions

How to best establish internal data release processes?

- Establish organisational policy on data sharing.
- Prepare as early as possible key decision makers for the required sign-off to approve data sharing in PPP.
- Identify and engage early in the process internal stakeholders that need to be involved in data sharing approval. Several functions may need to be consulted. Ask them to review all critical documents, such as the ICF and the DMP.
- Highlight the criteria for data release decision in the internal guidance. It should be clear who has the authority to sign-off on data release.
- Include a specific internal IMI/IHI liaison role. This role is instrumental in providing guidance on how to navigate internal data sharing clearance. Involve the legal departments in discussions and project planning.
- Include internal data owners in the planning of data sharing in order to incorporate their perspectives and avoid eventual issues/blockades.
- Consider creating/adapting internal tools to expedite internal review and approvals of data releases. This can result in significant time savings.

RESOURCES

3.1 Testimonial on internal company tool to facilitate release of data by Sean Turner
3.2 Data Sharing Policies of Vivli members
3.3 MSD Portal and procedure to Access to Clinical Trial Data / Public website and document
3.5 Involvement of Roles in Data Sharing Decisions

How to best select and identify which data to share in a PPP?

- Be sure to secure sufficient time in the project planning stages to discuss data sharing.
- Take into consideration the decision-making timelines within companies, as these will be time-consuming.
- Determine required data quality and selection processes as early as possible.
- Plan early triage of data. This can assess data quality, completeness, and/or standardisation level(s) to ensure that data match pre-defined criteria.
- Plan the resource efforts needed to ensure that data criteria are adhered to by consortium members.
- Consider and keep in mind the sustainability of data shared in a PPP, and the additional data generated in any project.

RESOURCES

1.5 Sharing Is Caring – Data Sharing Initiatives in Healthcare

CHALLENGES

CH1 PPP and Data Sharing Processes
CH2 Legal/IP
CH4 Security/IT
CH5 GDPR

CH3

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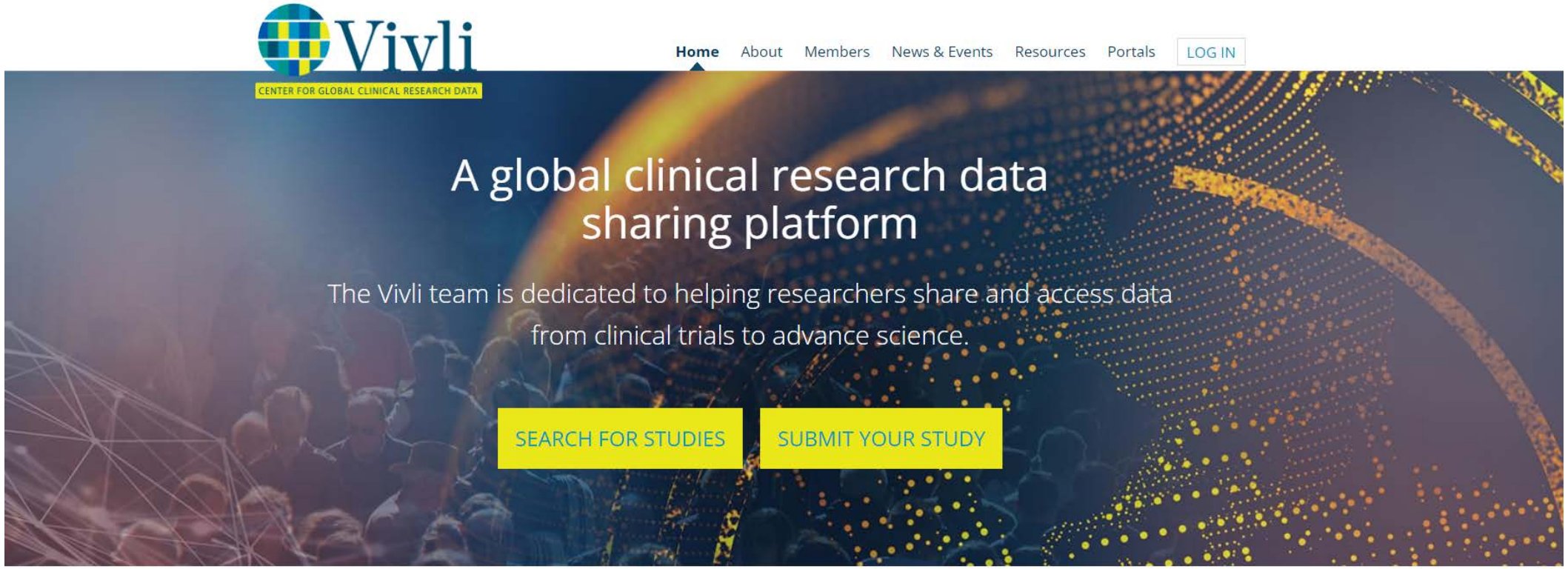

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CH3

Internal Processes

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Sharing Is Caring—Data Sharing Initiatives in Healthcare

Tim Hulsen

Author information ▸ Article notes ▸ Copyright and License information PMC Disclaimer

Abstract

Go to: ▸

In recent years, more and more health data are being generated. These data come not only from professional health systems, but also from wearable devices. All these 'big data' put together can be utilized to optimize treatments for each unique patient ('precision medicine'). For this to be possible, it is necessary that hospitals, academia and industry work together to bridge the 'valley of death' of translational medicine. However, hospitals and academia often are reluctant to share their data with other parties, even though the patient is actually the owner of his/her own health data. Academic hospitals usually invest a lot of time in setting up clinical trials and collecting data, and want to be the first ones to publish papers on this data. There are some publicly available datasets, but these are usually only shared after study (and publication) completion, which means a severe delay of months or even years before others can analyse the data. One solution is to incentivize the hospitals to share their data with (other) academic institutes and the industry. Here, we show an analysis of the current literature around data sharing, and we discuss five aspects of data sharing in the medical domain: publisher requirements, data ownership, growing support for data sharing, data sharing initiatives and how the use of federated data might be a solution. We also discuss some potential future developments around data sharing, such as medical crowdsourcing and data generalists.

Keywords: data sharing, data management, data science, big data, healthcare

Journal Article

Journal Article

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CH4

Security & Technology

INTRODUCTION & CONTEXT

Ensuring that required IT security criteria are met in PPPs can lead to delays in data sharing. The GDPR and increased digitalization mean that this may be perceived as less of an issue nowadays, but the focus on other areas also implies that the security requirements are often considered only very late in the project. Due to a lack of agreed IT and/or security standards and differing perspectives in consortia, IT security reviews often identify long lists of risks to be addressed.

FREQUENTLY ASKED QUESTIONS:

What [technical] environment will this PPP use to share data?

- Establish as early as possible (i.e., already in the grant proposal stage) the PPP data sharing concept at a high-level (i.e., central vs federated data storage).
- Consider open-source solutions that might be beneficial compared to proprietary solutions because of potential lock-in issues and/or lack of interoperability.
- Consider utilising a well-established and standardised Common Data Model(s) and platform(s) to enable data sharing and subsequent data usage(s). Budget for the data transformations needed to arrive at that model.
- Consider the reuse of proven solutions from previous PPP, rather than creating completely new platforms. The overhead involved in establishing legal frameworks, security reviews, etc. should not be underestimated.
- Consider early what analyses will be performed on the shared data within a PPP as this will have a strong impact on environment architecture decisions.

RESOURCES

3.5 Involvement of Roles in Data Sharing Decisions
4.1 IMI Criteria for sharing data
4.2 FAIR data principles
4.3 FAIR cookbook

What are the IT security requirements for this PPP?

- Consider IT security requirements based on well-established common standards (i.e., ISO) in parallel to legal and IP requirements. This could avoid lengthy and detailed reviews.
- Consider adding IT security requirements for transfer, hosting, and access as an annex to the Consortium Agreement (CA) or in the Data Management Plan (which is already an annex to the CA).
- Align IT security requirements in PPP and nominate one partner to conduct the IT security review for all in order to reduce overheads and/or delays.
- Discuss and agree the PPP data anonymisation strategy as early as possible (i.e., anonymisation, pseudonymisation, other). Also, be aware of significant differences in pseudonymisation standards between countries.
- Consider applying approved IT security standards. If this is not the case, the reasons for deviation should be clearly described and explained.

RESOURCES

4.1 IMI Criteria for sharing data
4.2 FAIR data principles
4.3 FAIR cookbook
4.4 ISO Information Security standards
4.5 ISO/TC 215 Health informatics
4.6 CDISC formatting for structured data
4.7 EOSC-Life Report on data standards
4.8 SEND format for harmonized structured preclinical data
4.9 Fast Healthcare Interoperability Resources (FHIR)
4.10 Health Level 7
4.11 OMOP Common data model
4.12 EHDEN 101: What is a federated data network? What is the OMOP common data model?
4.13 External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use
4.14 Health IT Standards

CHALLENGES

CH1 PPP and Data Sharing Processes
CH2 Legal/IP
CH3 Internal Processes
CH5 GDPR

CH5

General Data Protection Regulation (GDPR)

INTRODUCTION & CONTEXT

Concerns related to the GDPR within PPP's are frequent and can lead to significant issues concerning data sharing. Implementation of the GDPR has many country-specific, and company-specific interpretations which results in several different perspectives within almost all PPPs. International transfers outside the EU pose specific issues, relevant for companies with sites outside the EU (mostly in the US). In general, it is considered best practice to check upfront the alignment of Informed Consent Forms (ICF) with GDPR; the ability to share data inside and outside of the consortium; sharing of data geographically; the permission for secondary use of data in a project; and the applicability of data to the intended research purposes.

FREQUENTLY ASKED QUESTIONS:

What are the key best practices for addressing how the GDPR applies to a PPP?

- Consider that all PPPs with an important data sharing component must have an ethical/legal framework, an expert legal partner on board, and all partners sharing personal data should nominate a responsible person for data protection matters.
- Ensure that data protection officer(s) of the organisations are involved in the data sharing discussions.
- Consider using the same concepts and definitions in PPP agreements and documents as are described directly in the GDPR. Potentially these can be included as part of the PPP Data Management Plan.
- Map roles and accountabilities in the PPP data flow early on, in order to establish the data sharing concept.
- Establish roles and responsibilities in binding legal contracts (controller to processor agreements or joint controller agreements). The GDPR roles should reflect reality rather than the self-perceived roles in the project. This requires a detailed data flow analysis. The outcome could be that multiple parties are actually jointly responsible for the personal data (Joint Data Controllers). These agreements may be part of the Consortium Agreement.
- Consider that GDPR only applies to personal data. It is possible to share only fully anonymised data to ease data sharing. However, this can be limiting to the application(s) of data within projects.

RESOURCES

- 1.8 Schematic data flows with GDPR roles
- 3.5 Involvement of Roles in Data Sharing Decisions
- 5.1 European Data Protection Board Guidelines on the concepts of controller and processor
- 5.2 Key roles in GDPR
- 5.3 Introduction to anonymisation
- 5.4 IMI HARMONY Anonymisation Concept
- 5.5 Sharing Anonymised and Functionally Effective (SAFE) Data Standard for Safely Sharing Rich Clinical Trial Data
- 5.6 Report on Deploying Pseudonymisation Techniques by ENISA (European Union Agency for Cybersecurity)
- 5.7 TRANSCELERATE - A Privacy Framework for Clinical Data Reuse: Secondary Data Use in the Pharmaceutical Industry
- 5.10 Data Protection Impact Assessment

How to share data outside of the EU in compliance with the GDPR?

- Establish the necessary terms in standardised common and broad ICF template utilized in the PPP (only possible if data are actively collected; not for secondary use).
- Consider that, when sharing with non-EU sites of partners, pragmatically it can work best when the European site is the party receiving data access under the CA; the internal corporate binding contractual clauses can then be used for sharing onwards with the foreign sites.
- Implement a 1:1 contract between the data host or the data contributor and non-EU partner rather than consortium-wide agreements.
- Consider that recent legal rulings (SCHREMS II) severely limit the possibilities to share personal data outside the EU, but standard contractual clauses are still possible under SCHREMS II ruling. However, this requires an assessment of the local data protection of the foreign sharing partner (transfer impact assessment). SCCs can form part of the Data Sharing Agreement.

RESOURCES

- 5.8 The CJEU judgment in the Schrems II case by European Parliament
- 5.9 SCHREMS II Summary

CHALLENGES

CH1 PPP and Data Sharing Processes
CH2 Legal/IP
CH3 Internal Processes
CH4 Security/IT

CH5

General Data Protection Regulation (GDPR)

INTRODUCTION & CONTEXT

Concerns related to the GDPR within PPP's are frequent and can lead to significant issues concerning data sharing. Implementation of the GDPR has many country-specific, and company-specific interpretations which results in several different perspectives within almost all PPPs. International transfers outside the EU pose specific issues, relevant for companies with sites outside the EU (mostly in the US). In general, it is considered best practice to check upfront the alignment of Informed Consent Forms (ICF) with GDPR; the ability to share data inside and outside of the consortium; sharing of data geographically; the permission for secondary use of data in a project; and the applicability of data to the intended research purposes.

FREQUENTLY ASKED QUESTIONS:

What are the key best practices for addressing how the GDPR applies to a PPP?

- Consider that all PPPs with an important data sharing component must have an ethical/legal framework, an expert legal partner on board, and all partners sharing personal data should nominate a responsible person for data protection matters.
- Ensure that data protection officer(s) of the organisations are involved in the data sharing discussions.
- Consider using the same concepts and definitions in PPP agreements and documents as are described directly in the GDPR. Potentially these can be included as part of the PPP Data Management Plan.
- Map roles and accountabilities in the PPP data flow early on, in order to establish the data sharing concept.
- Establish roles and responsibilities in binding legal contracts (controller to processor agreements or joint controller agreements). The GDPR roles should reflect reality rather than the self-perceived roles in the project. This requires a detailed data flow analysis. The outcome could be that multiple parties are actually jointly responsible for the personal data (Joint Data Controllers). These agreements may be part of the Consortium Agreement.
- Consider that GDPR only applies to personal data. It is possible to share only fully anonymised data to ease data sharing. However, this can be limiting to the application(s) of data within projects.

RESOURCES

1.8 Schematic data flows with GDPR roles
3.5 Involvement of Roles in Data Sharing Decisions
5.1 European Data Protection Board Guidelines on the concepts of controller and processor
5.2 Key roles in GDPR
5.3 Introduction to anonymisation
5.4 IMI HARMONY Anonymisation Concept
5.5 Sharing Anonymised and Functionally Effective (SAFE) Data Standard for Safely Sharing Rich Clinical Trial Data
5.6 Report on Deploying Pseudonymisation Techniques by ENISA (European Union Agency for Cybersecurity)
5.7 TRANSCELERATE - A Privacy Framework for Clinical Data Reuse: Secondary Data Use in the Pharmaceutical Industry
5.10 Data Protection Impact Assessment

How to share data outside of the EU in compliance with the GDPR?

- Establish the necessary terms in standardised common and broad ICF template utilized in the PPP (only possible if data are actively collected; not for secondary use).
- Consider that, when sharing with non-EU sites of partners, pragmatically it can work best when the European site is the party receiving data access under the CA; the internal corporate binding contractual clauses can then be used for sharing onwards with the foreign sites.
- Implement a 1:1 contract between the data host or the data contributor and non-EU partner rather than consortium-wide agreements.
- Consider that recent legal rulings (SCHREMS II) severely limit the possibilities to share personal data outside the EU, but standard contractual clauses are still possible under SCHREMS II ruling. However, this requires an assessment of the local data protection of the foreign sharing partner (transfer impact assessment). SCCs can form part of the Data Sharing Agreement.

RESOURCES

5.8 The CJEU judgment in the Schrems II case by European Parliament
5.9 SCHREMS II Summary

CHALLENGES

CH1 PPP and Data Sharing Processes
CH2 Legal/IP
CH3 Internal Processes
CH4 Security/IT

3.5 Involvement of Roles in Data Sharing decisions

- *Several Roles intervene in the process to facilitate data sharing. This swim lanes tool visually identifies who should participate in each data sharing decision or action along the project life cycle.*
- *The main decisions and actions associated with the 5 data sharing challenge areas are described in each swim lane (1- PPP and Data Sharing Processes, 2- Legal/IP, 3- Internal Processes, 4- Security/IT, 5- GDPR).*
- *In the header, the main Roles involved are represented (definitions can be found in the Roles section). The user can click in any of the Roles displayed and the actions in which the Role should participate will be highlighted. By ticking the "Clear selection" button the tool will be cleaned.*

CLEAR SELECTION

	IMI liaison officer	GDPR expert	IT specialist	Therapeutic lead	Senior manager/ Academic Lead	Data Protection Officer (DPO)	Lawyer	Principal investigator	Statistician	Project leader	Project coordinator
	○	●	○	○	○	○	○	○	○	○	○

	TOPIC WRITING	PROPOSAL PREPARATION	GRANT AGREMENT PHASE	PROJECT EXECUTION
CH1 PPP and Data Sharing Processes	• Outline convincing business case for data sharing • Make an initial selection of potential datasets • Ally with experienced data sharers in the consortium • Train the project leadership team	• Involve staff with previous in-depth IMI experience • Involve the consortium in selection of data sets • Consider outsourcing support activities • Draw initial data flows	• Get guidance from the IMI liaison	• Prepare internal stakeholders organise data flow workshop
CH2 Legal/IP	• Identify type of data needed to address research question • Explore legal/IP limitations of data to be shared (which should be in line with the Access Rghts in the CA)	• Examine if trial data can be shared, rights on 3rd party are adequate and informed consent is sufficient • Involve legal experts	• Map project legal components • Append Template DSA/MTA in CA • Include Mandate to sign DSA	• Confirm understanding of Data Sharing principles in consortium • Set up legal agreements asap • Develop ICF for prospective data collection
CH3 Internal Processes	• Consult internal data sharing organisational policy & processes • Perform risk/reward analysis • Identify datasets internally • Ally with experienced colleagues • Involve internal stakeholders	• Secure senior management approval • Use impact demonstrators from other projects		• Involve all internal stakeholders; be aware of staff turnover • Start data sharing clearance to expedite process • Use internal data release tools
CH4 Security/IT	• Consider security of data needed to address research question • Select auditable standard	• Utlise Common Data Model and/or Platform for Data Sharing • Set IT security requirements • Agree on data anonymisation strategy • Identify solutions to be used for Data Sharing	• Add IT security requirements to CA (e.g. via the Data Management Plan or to be included in a DSA)	• Align IT security review process across EFPIA partners • Agree to data exchange formats (to be included in the Data Management Plan, the DSA/DTA)
CH5 GDPR	• Review Initial use and access	• Check ICF template • Plan if DS outside EAA is needed • Define and agree the roles of controller, joint controller and processor	• Include DPA and/or joint controller agreement template in CA	• Develop DMP in early phase • Conduct DPIA • Organize data flow workshop checking all assumptions made • Introduce SCC for outside EAA sharing

RESOURCES

The challenges in practice

Jan-Willem Boiten, Lygature

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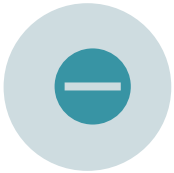
Interviews with 20+ key stakeholders from data-intense projects – why is data sharing a problem at all?

We tend to underestimate the problem – some red flags to illustrate this:



No problem; we already have a template

Let's put the lawyers together; they solve it

We have plenty of time

Let's discuss in a small group

We have lots of data; surely we can share it

We have a unique blend of central and federated data repositories

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Results of interviews generalised in best case scenario and worst case scenario

19

DataSharingPlayBook

CASE STUDY: A new IHI project is being proposed involving the integration of full clinical trial data (clinical + control) of previous company clinical trials.

TOPIC WRITING	PROPOSAL PREPARATION		GRANT AGREEMENT PHASE	PROJECT EXECUTION				
YEAR - 2	STAGE I — YEAR -1	STAGE II — YEAR -0,5	YEAR 0	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5

Best case scenario

- ✔ The partners come together in the consortium; scientifically there is a great match and enthusiasm about the wealth of data available. There are two data leaders to cater against staff moving out during the project.
- ✔ The selection criteria for the data sets to be shared within the project are agreed with the consortium.
- ✔ At a high-level, the data sharing concept between the organisations and the data hosting partner appears to be matching. The flow of data including the use and access criteria is being described in some detail. A comprehensive list of data sources is available indicating data formats, volume, ethical approval confirmation and key contacts. Drafts for Data Processing and Data Sharing agreements are circulated with legal colleagues.
- ✔ The IT departments of companies are involved and have nominated one party as the representative defining the security requirements for data sharing; this is defined as a deliverable for project month 12.

Worst case scenario

- The partners join the consortium and scientifically there is a great match and enthusiasm about the wealth of data available.
- ⚑ At a high-level the data sharing concept between the organisations and the hosting partner appears to be matching, but on the details, there are incompatible data sharing concepts proposed. It is decided to deal with those in the first 6 months of the project in the Data Management Plan.

Challenges FAQS and strategies

CHALLENGE 1
How to best avoid commonly see pitfalls related to data sharing in PPP?

CHALLENGE 2
How to construct effective legal frameworks in PPP consortia efficiently?

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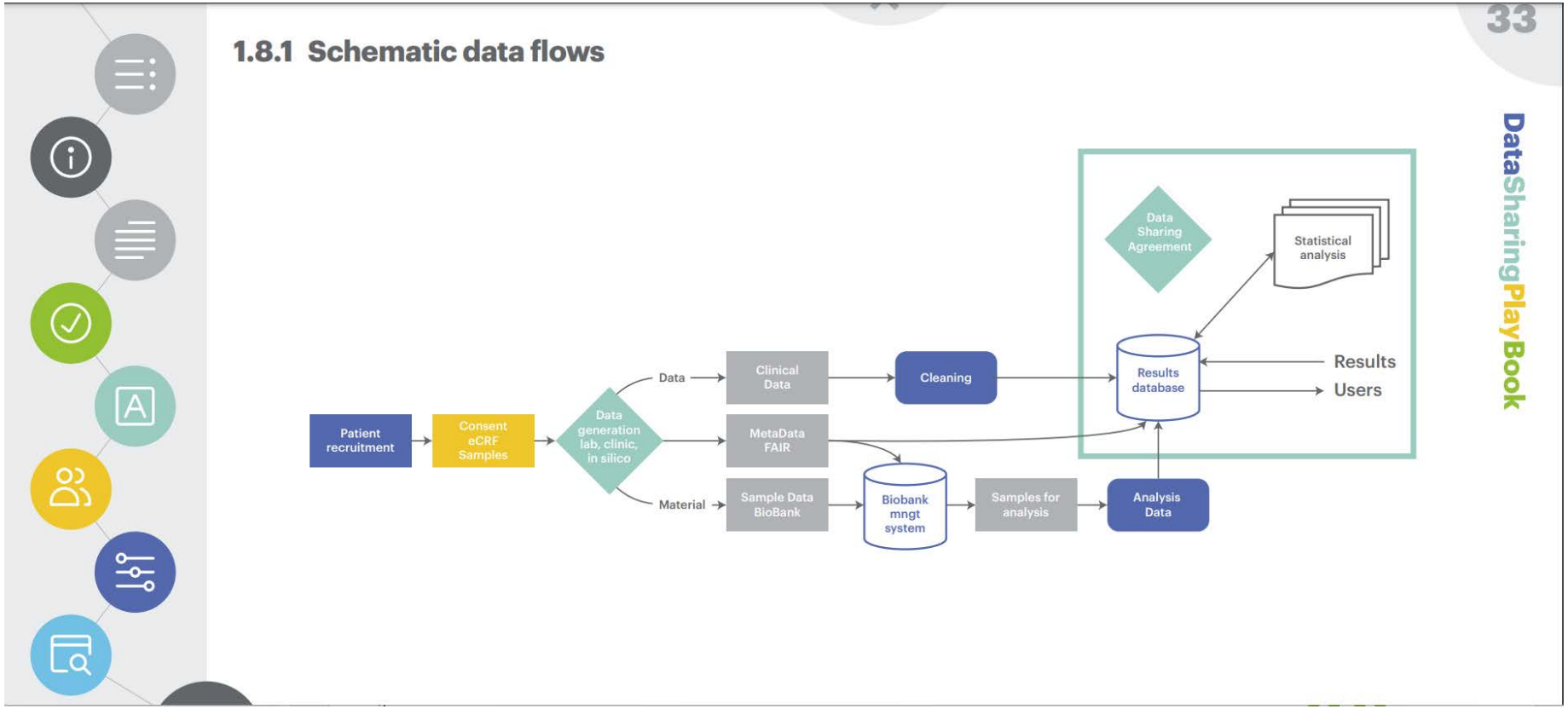
It all starts with common understanding on data flow

Usually captured in data management plan



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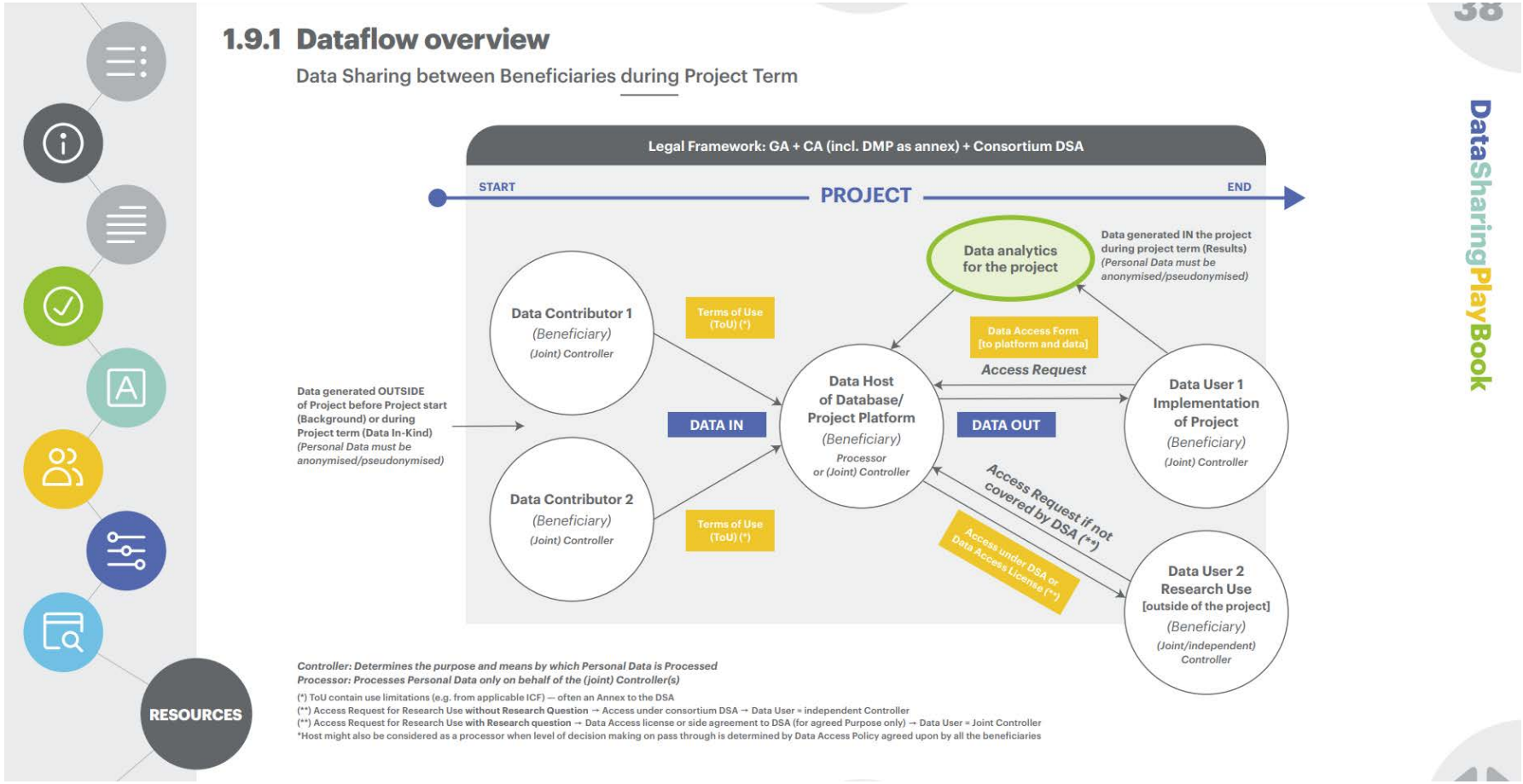
Legal agreements follow from the dataflow



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Key messages derived from interviews

- Data sharing is not rocket science, but don’t underestimate it
- Start early!
- It is a matter of project management rather than a legal problem
- **#1 recommendation** – Start with the data flow

Data sharing masterclass

OPTIMA use case

Andreas Kremer, Carla Goddard
04.09.2024 • IHI Data sharing masterclass• Virtual session

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The playbook gives you a shared language

Fundamental concepts

Identifiable patient level data
Information recorded on individuals that allows direct or indirect tracing to patients/participants. In a clinical trial context, this would include patient personal details, site, outcomes, etc.

Pseudonymised personal data R 5.6
Personal data that has gone through a 'pseudonymisation' process by which it can no longer be traced back to a specific individual (data subject) without the use of additional information. In most countries pseudonymised data is still considered personal data.

Pseudonymisation R 5.6
The processing of personal data in such a manner that it cannot longer be attributed to a specific individual (data subject) without the use of additional information. Such additional information must be kept separate and subject to technical and organisational measures. For instance, data allowing for direct identification are replaced with a code which is then stored in a separate location (i.e., a table). Data subject to Pseudonymisation is Pseudonymised Data.

Anonymised data R 5.3 - R 5.4 - R 5.5
Personal data that has gone through the process of removing sufficient information elements so that the individuals (data subjects) are not identifiable and cannot be re-identified by any means reasonably likely to be used (i.e., the risk of re-identification is sufficiently remote). Anonymous information is not personal data and data protection law does not apply.

Synthetic data
Data that has been artificially created by computer simulations and/or algorithms. These data mimic real-world data but without personal data or any IP-sensitive data elements.

Primary data R 5.7
Data directly collected from first-hand sources through different methods —surveys, interviews, experiments—, with a specific research purpose. Although collecting primary data is usually expensive and time-consuming, it ensures rights and control over the type of data to be generated and standards used.

Secondary use of data R 1.3 - R 5.7
Data previously collected and made available for others to use. This may include data generated by government, research, or healthcare institutions that are now used for a generic or different purpose than the one for which it was originally collected.

Federated hosting of data R 1.8
This model allows multiple distributed data sources to function as one. The federated network takes data from a range of sources that have been standardised to a common data model. This approach allows partners to query data from multiple sources. Yet, special attention needs to be paid to data standardisation, maintenance, and connectivity aspects.

Centralised hosting of data R 1.8
This model implies that the data are located, stored, and maintained in a single location. This approach often ensures the quality of the data, but costs, geographical location, and compliance with business and legal requirements can prove challenging.

Controller R 5.1 - R 5.2
A role defined in the GDPR as "the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data". (i.e., the person or organisation that determines the purpose(s) for which personal data are processed and how such processing is to be done). A key role of the controller is to allocate responsibilities (i.e., who shall oversee compliance with data protection rules, and how data subjects can exercise their data ownership rights in practice).

Joint controller R 2.6 - R 5.1 - R 5.2
This role involves two or more organisations who jointly determine 'why' and 'how' personal data should be processed, which can be either by a common decision or by converging decisions. Since the responsibilities of joint controllers do not need to be equal, GDPR requires the joint controllers to clearly establish their respective responsibilities in what is usually called a joint controller arrangement.

Processor R 5.1 - R 5.2
A role defined in the GDPR as "a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller". A processor may engage another processor (a "sub-processor") for specific tasks, but only after formal authorization by the controller. The mandate of the processor needs to be specified in a data processing agreement between the controller and the processor.

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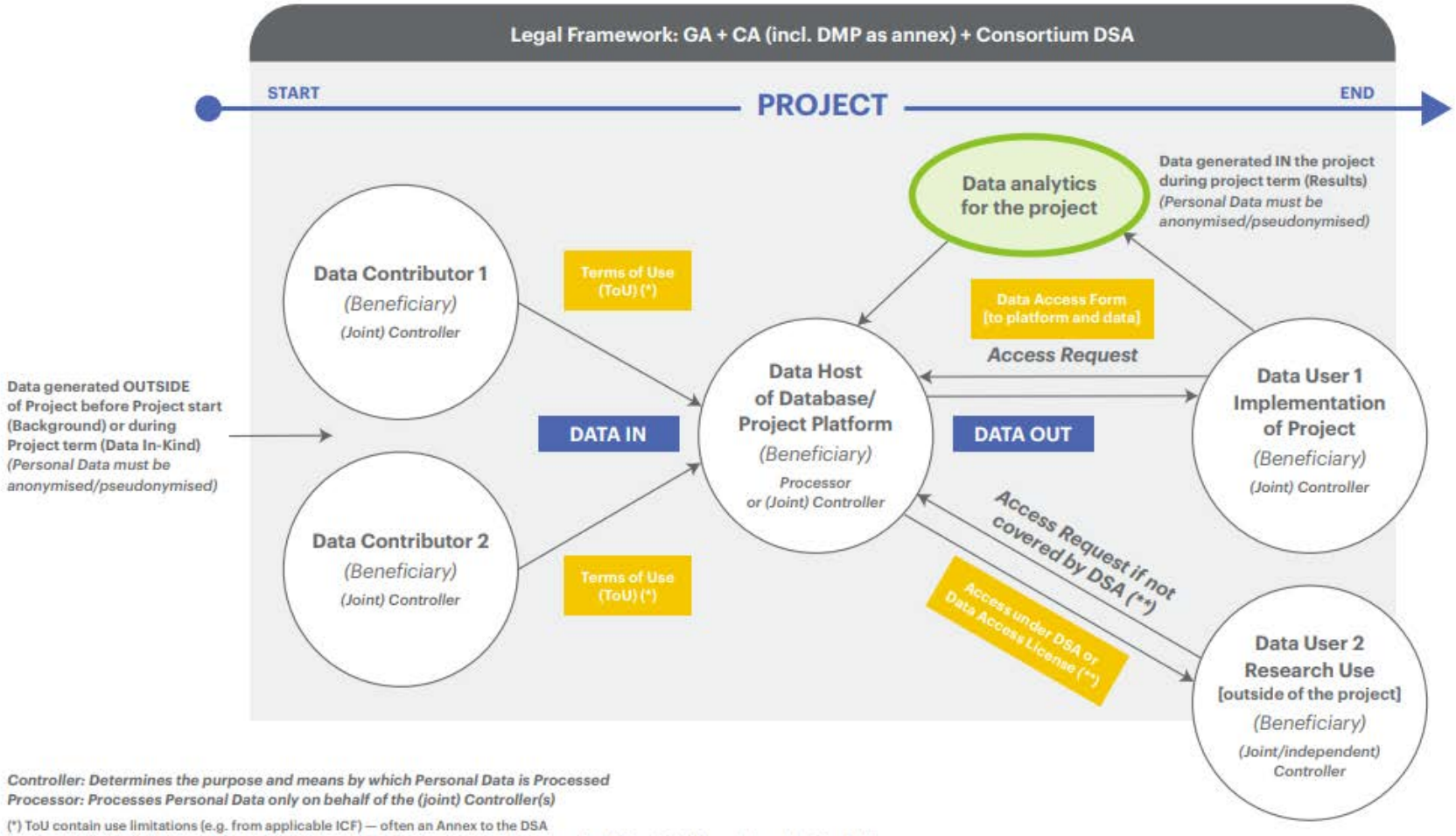
Identify early where you are “in the game”

Dataflow overview

Data Sharing between Beneficiaries during Project Term



Controller: Determines the purpose and means by which Personal Data is Processed
Processor: Processes Personal Data only on behalf of the (joint) Controller(s)

(*) ToU contain use limitations (e.g. from applicable ICF) — often an Annex to the DSA
(**) Access Request for Research Use **without Research Question** → Access under consortium DSA → Data User = independent Controller
(**) Access Request for Research Use **with Research question** → Data Access license or side agreement to DSA (for agreed Purpose only) → Data User = Joint Controller
*Host might also be considered as a processor when level of decision making on pass through is determined by Data Access Policy agreed upon by all the beneficiaries

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The appropriate planning of security is critical to achieving timelines and ensuring data is shared

CH4

Security & Technology

INTRODUCTION & CONTEXT

Ensuring that required IT security criteria are met in PPPs can lead to delays in data sharing. The GDPR and increased digitalization mean that this may be perceived as less of an issue nowadays, but the focus on other areas also implies that the security requirements are often considered only very late in the project. Due to a lack of agreed IT and/or security standards and differing perspectives in consortia, IT security reviews often identify long lists of risks to be addressed.

FREQUENTLY ASKED QUESTIONS:

What [technical] environment will this PPP use to share data?

- Establish as early as possible (i.e., already in the grant proposal stage) the PPP data sharing concept at a high-level (i.e., central vs federated data storage).
- Consider open-source solutions that might be beneficial compared to proprietary solutions because of potential lock-in issues and/or lack of interoperability.
- Consider utilising a well-established and standardised Common Data Model(s) and platform(s) to enable data sharing and subsequent data usage(s). Budget for the data transformations needed to arrive at that model.
- Consider the reuse of proven solutions from previous PPP, rather than creating completely new platforms. The overhead involved in establishing legal frameworks, security reviews, etc. should not be underestimated.
- Consider early what analyses will be performed on the shared data within a PPP as this will have a strong impact on environment architecture decisions.

RESOURCES

3.5 Involvement of Roles in Data Sharing Decisions
4.1 IMI Criteria for sharing data
4.2 FAIR data principles
4.3 FAIR cookbook

What are the IT security requirements for this PPP?

- Consider IT security requirements based on well-established common standards (i.e., ISO) in parallel to legal and IP requirements. This could avoid lengthy and detailed reviews.
- Consider adding IT security requirements for transfer, hosting, and access as an annex to the Consortium Agreement (CA) or in the Data Management Plan (which is already an annex to the CA).
- Align IT security requirements in PPP and nominate one partner to conduct the IT security review for all in order to reduce overheads and/or delays.
- Discuss and agree the PPP data anonymisation strategy as early as possible (i.e., anonymisation, pseudonymisation, other). Also, be aware of significant differences in pseudonymisation standards between countries.
- Consider applying approved IT security standards. If this is not the case, the reasons for deviation should be clearly described and explained.

RESOURCES

4.1 IMI Criteria for sharing data
4.2 FAIR data principles
4.3 FAIR cookbook
4.4 ISO Information Security standards
4.5 ISO/TC 215 Health informatics
4.6 CDISC formatting for structured data
4.7 EOSC-Life Report on data standards
4.8 SEND format for harmonized structured preclinical data
4.9 Fast Healthcare Interoperability Resources (FHIR)
4.10 Health Level 7
4.11 OMOP Common data model
4.12 EHDEN 101: What is a federated data network? What is the OMOP common data model?
4.13 External guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use
4.14 Health IT Standards

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Acknowledge IMI

OPTIMA is supported by the Innovative Medicines Initiative, a partnership between the European Union and the European pharmaceutical industry.

IHI IDERHA PROJECT

Philip Gribbon, Head of Discovery Research, Fraunhofer Institute for Translational Medicine and Pharmacology (ITMP)

María Bardají- Cruz, Senior Manager, Global Privacy Team, Johnson & Johnson

04th September 2024

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IDERHA mission

Integration of heterogenous Data and Evidence towards Regulatory & HTA Acceptance

'In IDERHA we will be an open, disease agnostic, federated data space which enables connectivity, access, use and reuse of digital health data, and develop consensus policy recommendations on health data access and heterogeneous health research (e.g. RWE) for regulatory and HTA decision-making.'

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IDERHA goals

1. A **federated data space** for the seamless access to diverse health data.
2. **AI/ML algorithms**, validated on EU data sets, to support more efficient and accurate risk profiling, malignancy risk prediction, diagnosis, and prognosis on **lung cancer**.
3. A **digital application** to **remotely monitor the individual patient** post-discharge **health status**.
4. Extension of the **OMOP** common data model.
5. Enabling **personal health data environment**, bridging the gaps in the current standards and **FAIRification** framework including necessary extensions of standards.
6. Subject's **specific health data connected, and accessible** for secondary use.
7. Consensus on **policy recommendations** for the development of **laws, guidelines and policies** adapted to the current and future states of digitalisation, and consistent with **secondary use of health data** for **research and innovation**, as well as acceptability of **RWD for regulatory** and **HTA decision making**.

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Interconnectivity

IMI/IHI Projects

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

Johnson&Johnson · ITTM Information Technology for Translational Medicine · Instituto de Investigación Sanitaria La Fe · Servicio Andaluz de Salud CONSEJERÍA DE SALUD

SERVICIO ANDALUZ DE SALUD Consejería de Salud y Consumo · Helios · NICE National Institute for Health and Care Excellence · EPF European Patients Forum

OPTIMA

Roche · ERS EUROPEAN RESPIRATORY SOCIETY every breath counts · European Cancer Patient Coalition

Helios · ITTM Information Technology for Translational Medicine · EHDEN EUROPEAN HEALTH DATA & EVIDENCE NETWORK

EU-PEARL
EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

Johnson&Johnson · sanofi · ITTM Information Technology for Translational Medicine · EPF European Patients Forum

H_2O HEALTH OUTCOMES OBSERVATORY

Takeda · i-HD The European Institute for Innovation through Health Data · sanofi

Roche · EPF European Patients Forum

EU Data Standards

FAIRplus

Fraunhofer · elixir · Johnson&Johnson

lygature pioneering medicine. together. · i-HD The European Institute for Innovation through Health Data · PHILIPS

GAIA-X
data-infrastructure.eu

Fraunhofer · PHILIPS

INTERNATIONAL DATA SPACES ASSOCIATION

Fraunhofer · VTT

Global Alliance for Genomics & Health
Collaborate. Innovate. Accelerate.

elixir

EU Health Data Space Public Partner

EPF European Patients Forum

elixir

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

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IDERHA Secure Data Processing Architecture Principle

Based on standards, enabling interoperability & easy re-use of existing solutions incl. FAIR, GA4GH* & IDSA**

Sending Analysis Request

Receiving the Results of the Analysis

Data Request / Analysis Tool, Requester Identity

Results / Insights

Receiving Analysis Request
Authorising data access

Source Data is ACCESSED not SHARED

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* GA4GH: Global Alliance for Genomics and Health (GA4GH) sets standards and frames policies to expand genomic data use: www.ga4gh.org
** internationaldataspaces.org

Data Access Opportunities

- IDERHA partners via federation
  - IIS La Fe, SERGAS….)
- IDERHA-linked networks via agreements
  - FinData via VTT…
  - European Respiratory society via MSB
  - EUCAIM community via IIS La Fe
  - EHDEN/OMOPed data via ITTM, (see OPTIMA)
- External data access providers and users of the platform
  - Academic (algorithm developers)
  - Clinical (Secondary use – establish best practices)
  - Industry (enabling collaborations)
- Organised via the IDERHA “Clinical Data Network”

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Data Access: Key challenges and approaches

- Previous experience on challenges of Data Access
  - FAIRplus – 20 IMI projects – Learning included in DSP !
- Establishing a scalable data governance model
  - „Internal“ data holders – Use cases / Demonstrate value
  - „External“ data holders (ongoing) – Future customers / Sustainability
- Aligning across EU countries and individual organisational needs
- Aligning to emerging regulations (AI act and EHDS)
- Consortia Agreement designed with IDERHA‘s specific requirements in mind
  - Internal and external Data Sharing Framework identifed
  - Role of the DMP defined

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Data Sharing Framework

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Legal framework

- IDERHA Grant Agreement (GA)
- IDERHA Consortium Agreement (CA)
  - Art. 4.10 introduced- committment of parties to agree on DMP
- Data Sharing Framework:
  - **Data Management Plan (DMP) +**
  - **Joint Controller Agreement (JCA)**

GRANT AGREEMENT

CONSORTIUM AGREEMENT

As part of the CA, it is legally binding!

IDERHA DMP

The DMP is a 'living' document that outlines how research data, incl. PII collected or generated will be handled during and after a research project. The DMP should gain substance as the project progresses.

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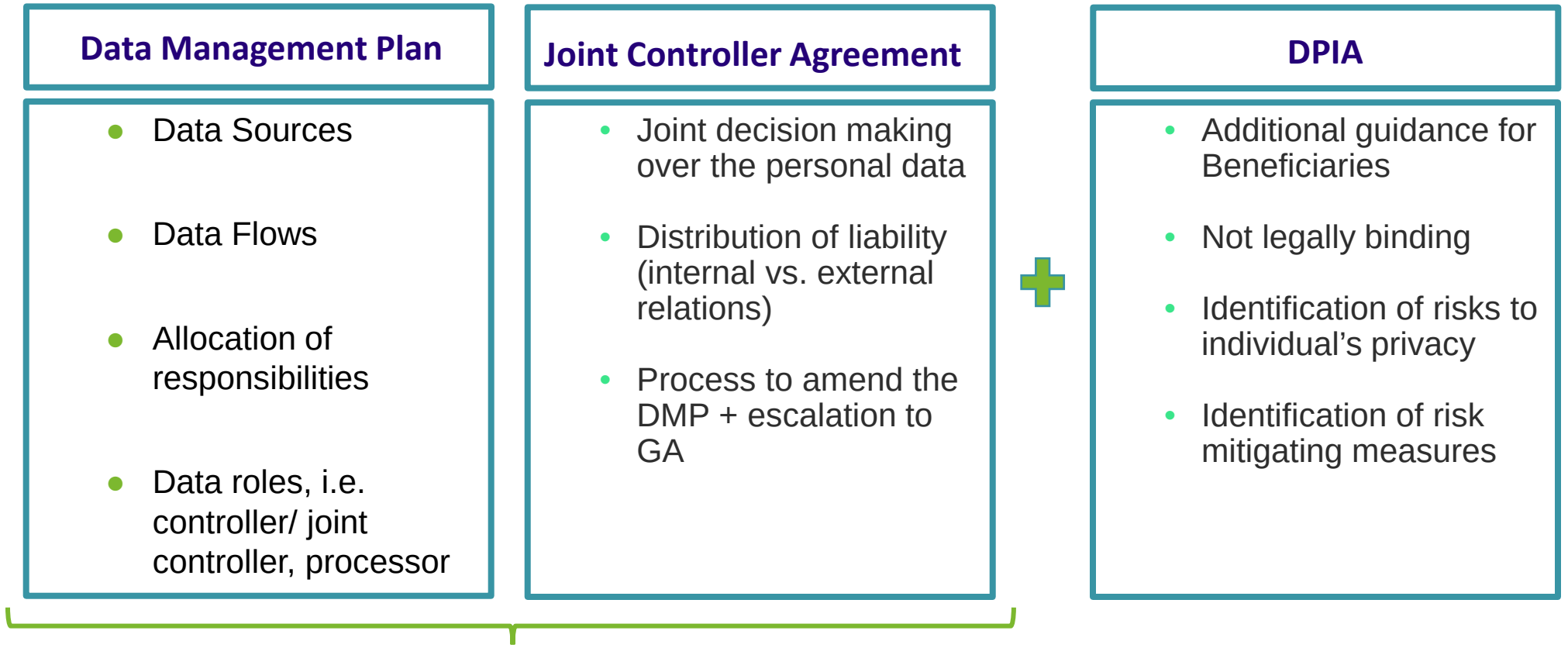
Slide: Effi Vandevoorde, Senior Legal Counsel, J&J Innovative Medicine

Data Sharing Framework



Arts. 4.10 and 4.15 of the Consortium Agreement
enter into an appropriate additional agreement on the processing of personal data

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Joint Controller Agreement+ DMP

Joint determination of means and purposes- Arts. 26, 82 GDPR

Point of Fact

Data Management Plan

Accountability

- ✓ Processing activities under each Party's responsibilities
- ✓ Sources, nature and scope of the Personal Data which the Party contributes to the Project, either directly or indirectly
- ✓ Whether any statutory and/or contractual relationship exists between a Data Holder and a third party
- ✓ Whether Party is contributing data directly or indirectly

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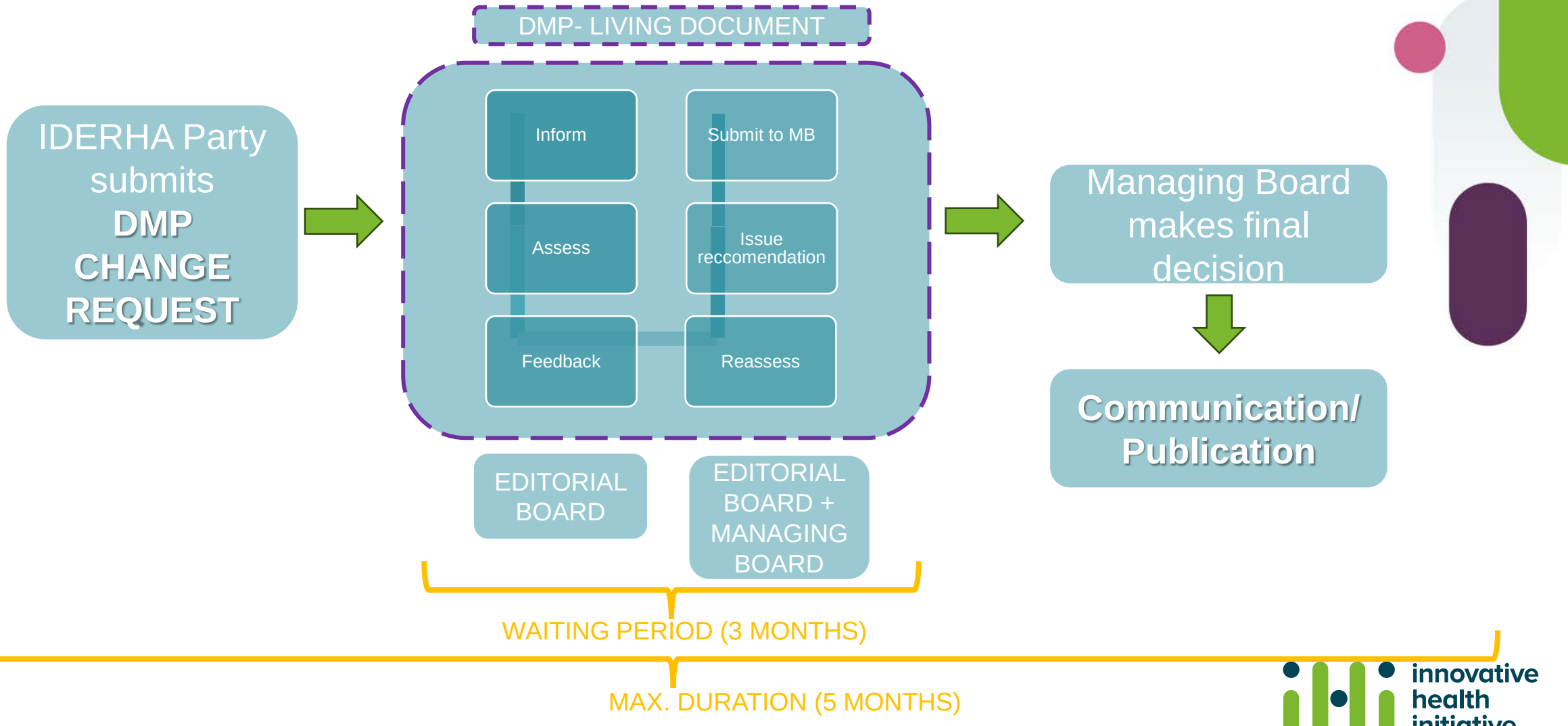
Joint Controller Agreement+ DMP



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Key Takeaways. What have we learnt?

- **Involvement of legal/ privacy stakeholders** from project proposal onwards **facilitates communication and alignment** of the parties which in turn leads to timely development of applicable data sharing frameworks

- Early **definition of data flows and assessment of roles** based on **factual analysis** is decisive for beneficiaries onboarding and to ensure **transparency** on responsibilities and derived liability

- Data Management Plan **incorporated in CA as a commitment** from parties reinforces the central role of the document

- Data Management Plan shall act as **single source of truth allows** for sustainability and flexibility

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Moving forward- ideas

- Evolving regulatory landscape, incl. EHDS, AI Act, Data Act, and NIS2, calls for **heightened attention to privacy and data protection considerations in data-sharing scenarios-** increased compliance risks

- Creation/ development of privacy and data protection **standards for collaborative environments**.

- The development of further tools, contract templates, and resources to **facilitate communication and negotiation within collaborative environments** and which will develop the Data Sharing Playbook.

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Thank you for your attention

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COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union