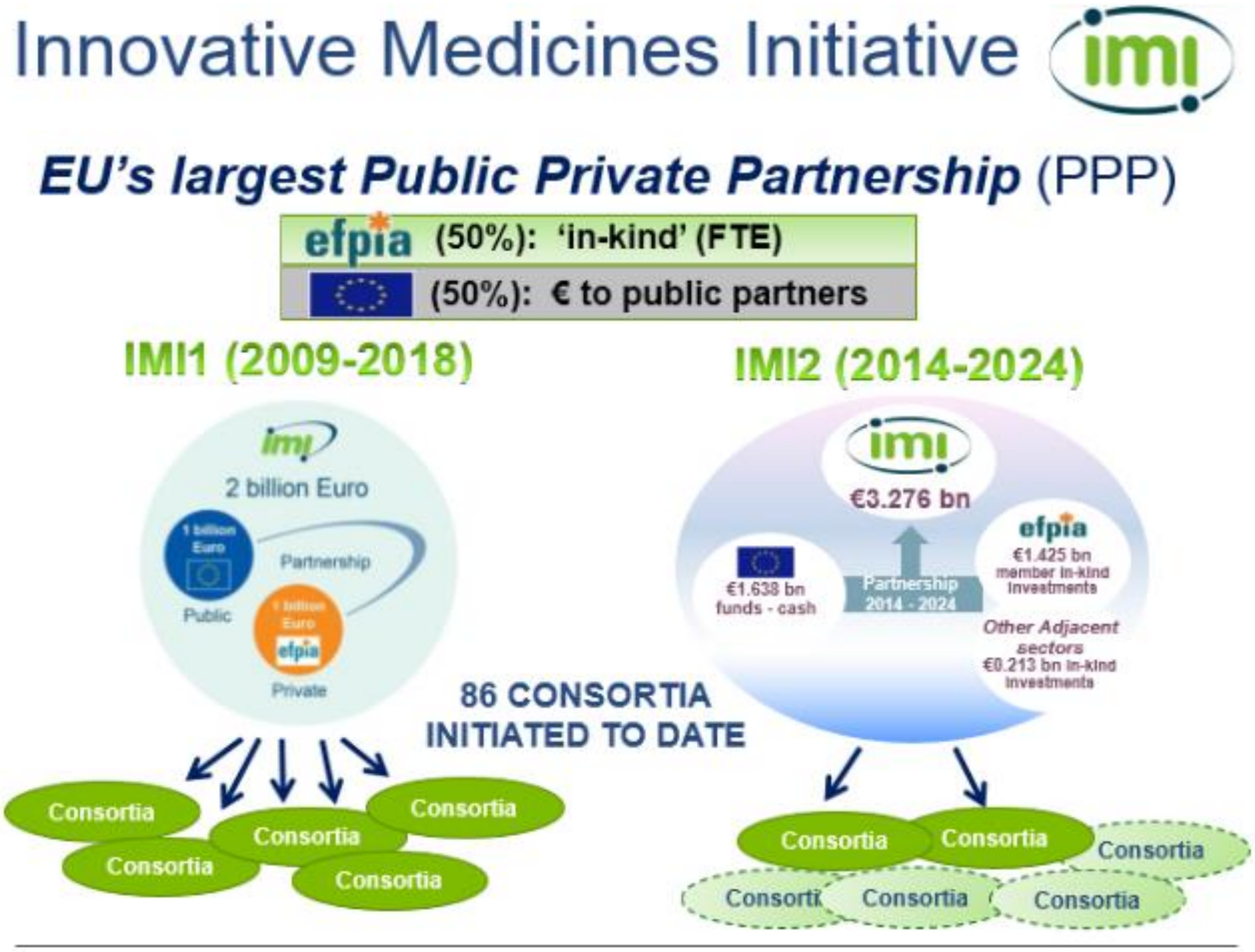
SEMINARIO CEFI - IMPACTO DE LA NUEVA REGULACIÓN DE PROTECCIÓN DE DATOS EN LA INVESTIGACIÓN BIOMÉDICA

PERSPECTIVA EUROPEA Y PROYECTOS IMI

26/06/2018, Cecilia Álvarez Rigaudias

Proyectos IMI



Innovative Medicines Initiative imi

EU's largest Public Private Partnership (PPP)

efpia	(50%): 'in-kind' (FTE)
🇪🇺	(50%): € to public partners

IMI1 (2009-2018)

imi

2 billion Euro

1 billion Euro

Public

Partnership

1 billion Euro

efpia

Private

Consortia

Consortia

Consortia

Consortia

Consortia

86 CONSORTIA INITIATED TO DATE

IMI2 (2014-2024)

imi

€3.276 bn

€1.638 bn funds - cash

Partnership 2014 - 2024

efpia

€1.425 bn member in-kind investments

Other Adjacent sectors

€0.213 bn in-kind investments

Consortia

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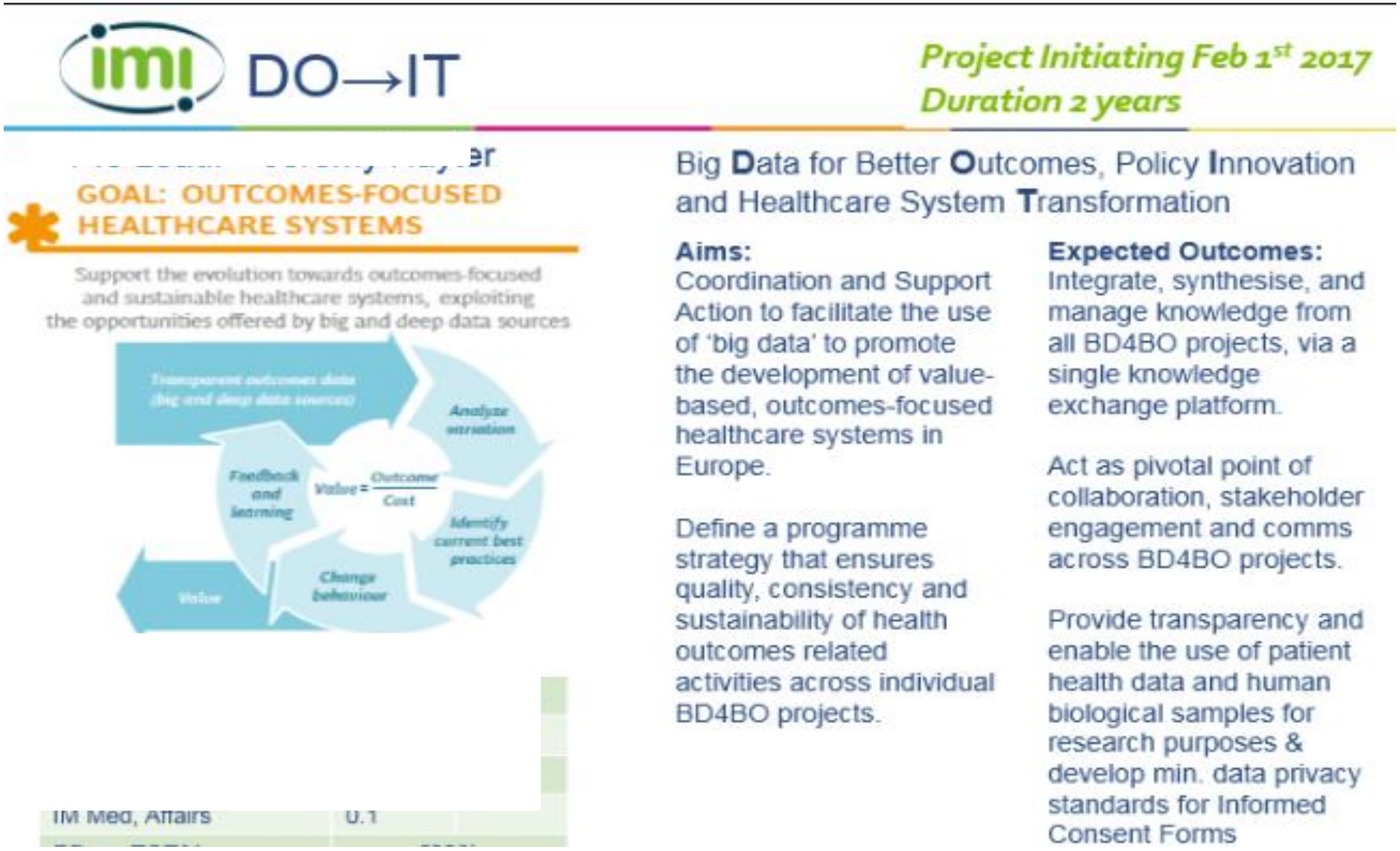
Proyecto DO-IT (IMI)

DO-IT project is an IMI2 project that is part of the broader strategic “Big Data 4 Better Outcomes (BD4BO)” initiative



imi DO→IT

Project Initiating Feb 1st 2017
Duration 2 years

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GOAL: OUTCOMES-FOCUSED HEALTHCARE SYSTEMS

Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by big and deep data sources

IM Med, Affairs	0.1

Big **D**ata for Better **O**utcomes, Policy **I**nnovation and Healthcare System **T**ransformation

Aims:

Coordination and Support Action to facilitate the use of ‘big data’ to promote the development of value-based, outcomes-focused healthcare systems in Europe.

Define a programme strategy that ensures quality, consistency and sustainability of health outcomes related activities across individual BD4BO projects.

Expected Outcomes:

Integrate, synthesise, and manage knowledge from all BD4BO projects, via a single knowledge exchange platform.

Act as pivotal point of collaboration, stakeholder engagement and comms across BD4BO projects.

Provide transparency and enable the use of patient health data and human biological samples for research purposes & develop min. data privacy standards for Informed Consent Forms

Proyecto DO-IT (IMI)

IMI2-DO→IT is the Coordination and Support Action (CSA) under IMI's Big Data for Better Outcomes (BD4BO) programme.

The overall goal is to facilitate the use of 'big data' to promote the development of value-based, outcomes-focused healthcare systems in Europe. **To fully exploit the transformative potential of big data, consideration will need to be taken of the use of detailed personal and biological information across the spectrum of care delivery**, starting from the development of innovative medicines and treatments, to market access and adoption, diffusion, and use in healthcare systems by providers and patients. **This paradigm shift requires shared understanding and standards among healthcare stakeholders** including patients, providers, payers, regulators, policy makers, pharmaceutical industry, and academia.

Proyecto DO-IT (IMI)

IMI-DO→IT will establish an enabling platform that brings together these stakeholder groups across the BD4BO programme to ensure quality and consistency of individual projects in line with the overarching programme objective:

· Define a programme strategy that ensures quality, consistency and sustainability of health outcomes related activities across individual BD4BO projects.

· Integrate, synthesise, and manage knowledge from all BD4BO projects, making it easily accessible via a single knowledge exchange platform.

· Act as pivotal point of collaboration, stakeholder engagement and communication for all BD4BO projects.

· **Provide transparency and enable the use of patient health data and human biological samples for research purposes by developing minimum data privacy standards for Informed Consent Forms (ICFs) and supporting materials for use by individual BD4BO disease-specific programmes and more widely in the R&D sector.**

Proyecto DO-IT (IMI) – WP4

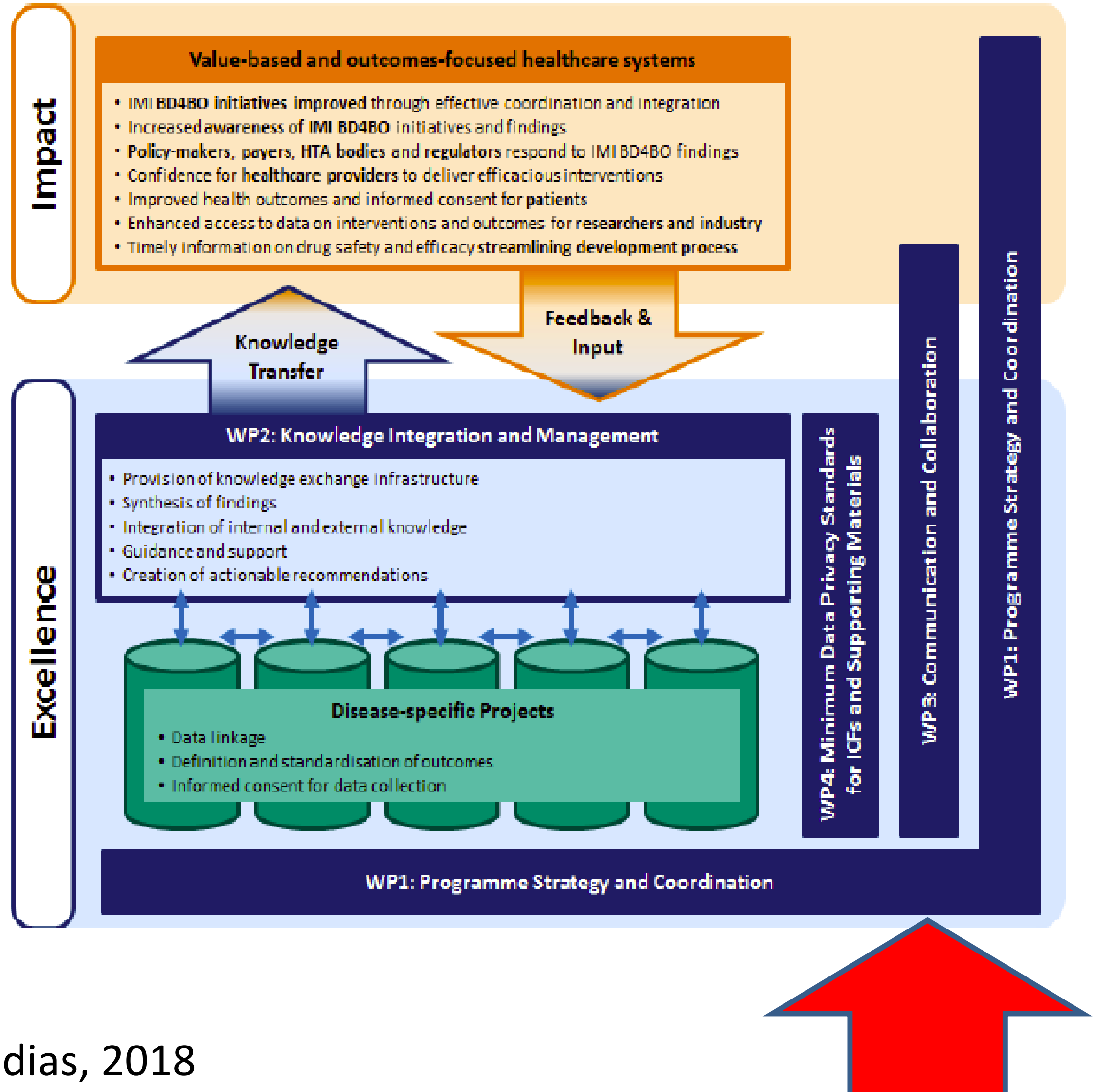


Figure 1: Conceptual Framework for the CSA of the Big Data for Better Outcomes Programme

Value-based and outcomes-focused healthcare systems

- IMI BD4BO initiatives improved through effective coordination and integration
- Increased awareness of IMI BD4BO initiatives and findings
- Policy-makers, payers, HTA bodies and regulators respond to IMI BD4BO findings
- Confidence for healthcare providers to deliver efficacious interventions
- Improved health outcomes and informed consent for patients
- Enhanced access to data on interventions and outcomes for researchers and industry
- Timely information on drug safety and efficacy streamlining development process

WP2: Knowledge Integration and Management

- Provision of knowledge exchange infrastructure
- Synthesis of findings
- Integration of internal and external knowledge
- Guidance and support
- Creation of actionable recommendations

Disease-specific Projects

- Data linkage
- Definition and standardisation of outcomes
- Informed consent for data collection

Proyecto DO-IT (IMI) – WP4

WP4, Minimum Data Privacy Standards for ICFs and Supporting Materials, recognises the common challenges of patient informed consent, data privacy and related regulations facing big data initiatives in health. This WP will deliver a common set of minimum data privacy standards for informed consent forms (ICF), explanatory information for their use, and training materials for patients, through a team of subject matter experts.

As the generation of the documents and materials described above requires aligment not only between all stakeholders involved in the healthcare sector but also beyond national jurisdictions in a cross-border approach, a main focus of WP4 is to engage with all stakeholders in a European setting, to foster discussion and to ensure buy in.

This will be achieved through an empirical review of current practices at the beginning of the project and continuous dialogue with the DPECs throughout the working process. Besides the alignment on data privacy standards and their implementation on an EU level, the WP focuses on strong patient involvement in the development of WP4 materials by involving sample participant focus groups. WP4 will strive to maintain regular consultation with the BD4BO projects and other related data privacy initiatives (e.g. EUPATI) for alignment and coordination purposes throughout the duration of the project. Finally, in collaboration with WP3 the deliverables of WP4 will be disseminated to the public.

Proyecto DO-IT (IMI) – WP4

Deliverables

- ICF (in paper / not electronic!)

- Explanatory memorandum

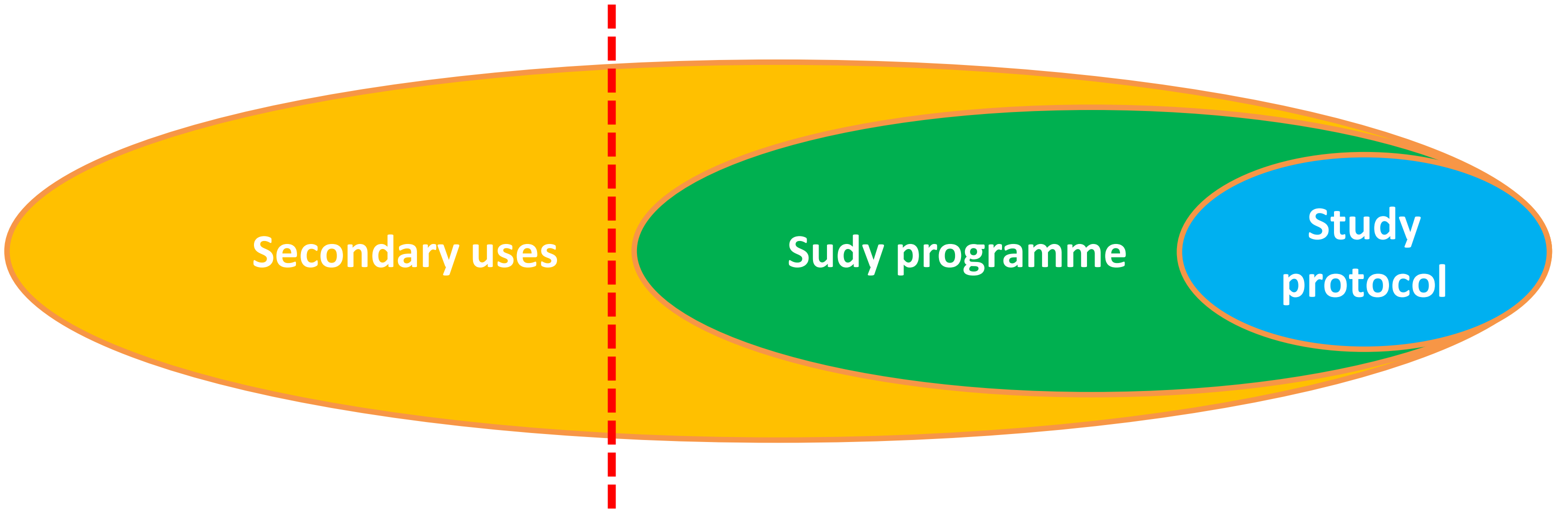
Proyecto DO-IT (IMI) – WP4

WP4 Discussions

- Embedded in the ICF / Separate Annex ?
- Cutting exercise – Layered approach
- Drawings (codification process)
- Patient language:
  - what is personal data … for the patient?

Proyecto DO-IT (IMI) – WP4

WP4 Discussions



Scope of use and legal basis:
- Consent? [and withdrawal]
- Public interest?
- Scientific research exemption?
- Legitimate interests?

Proyecto DO-IT (IMI) - WP4 – Member States divergences

	Criterio	Uso de datos personales en el ensayo	Usos futuros inv. científica
Alemania	Ley alemana GDPR	Consentimiento o Art. 9.2.j) (investigación científica), si interés legítimo + salvaguardas ley local conforme al art. 89	
España	Aut. sanitaria	Consentimiento de protección de datos inextricablemente unido al consentimiento a participar en el ensayo. [En proceso de consulta a la AEPD si la base legal debe ser otra]	Consentimiento [En proceso de consulta a la AEPD]
	AEPD (informe 073667/2018)	Consentimiento amplio o Art. 9.2.j) (investigación científica + art. 89)	
Francia	Aut. protección de datos	Art. 6 (int. púb. / int. leg.) + Art. 9.2.j) (investigación científica + art. 89) No se debe utilizar el consentimiento	[Posición desconocida]
Holanda	Aut. sanitaria	Consentimiento separado (del consentimiento a participar en el ensayo)	Consentimiento o Art. 9.2.j) (investigación científica + art. 89)
Reino Unido	Aut. sanitaria	Art. 6 (int. púb. para sector pub. / int. leg. para sector privado) No se debe utilizar el consentimiento (y están denegando ensayos clínicos que utilizan el consentimiento)	
Rep. Checa	Aut. protección de datos	Art. 9.2.i) (int. púb.) Consentimiento no necesario	[Posición desconocida]

Proyecto DO-IT (IMI) – WP4

WP4 Discussions

Other regulations:

- Biosamples
- Genetic data
- National development of art. 9.4, 9.2.h), art. 9.2.j) and art. 89 GDPR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