FACILITATE

FrAmework for ClinIcal triaL partIcipants' daTa reutilizAtion for a fully Transparent and Ethical ecosystem

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101034366. The JU receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

FACILITATE

DURATION
4 years, starts 1 January 2022

BUDGET
€ 3.260.000 EU contribution, € 3.363.904 In-kind

PARTNERSHIP 28 partners from 16 countries
20 UE (Italy, Austria, Belgium, Finland, France, Germany, Netherland, Czech Rep., Poland, Romania, Spain, Sweden) and 7 extra-UE (Serbia, Switzerland, USA, UK)

PUBLIC/PRIVATE - 17 partners
4 Universities/Research Centers, 6 Hospitals,
3 representatives of patients/citizens, 5 SMEs

INDUSTRIAL - 11 EFPIA members
9 Pharma, 1 Services →
More companies are expected by month 18

BOARDS
3 Decision Experts Committees: Patient Associations, Ethical committees, Data protection authorities, National Medicine/Drug Regulators, Healthcare professionals, Researchers, Geneticists

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Main objectives

Striking a Balance: Legal Constraints and Ethical Protection for the Return of and Secondary Use of data in Clinical Research

Shaping a patient-driven trusted legal and ethical ecosystem and building an actionable prototype process to sustain the return and reuse of clinical trial data

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FACILITATE's DRIVING FORCE for CHANGE

CONTRAST THE STATUS QUO

How to reconcile Big Data and Privacy

Could good faith GDPR legal safeguards make *de facto* Europe noncompetitive?

TRUST	the basis for well functioning data return and reuse
Privacy by design and default	(precludes predictive analytics)
Right to opt out	(but how?)
Informed (really informed?) consent	(impossible to predict to what I am giving consent to)
Data ownership – personal / public / private	**(issue is not on ownership but on access)**
Need access to enough "good quality data"	**impossible** with limits above

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Purpose & direction of FACILITATE

FACILIATE aims at addressing in a solution-based methodology the following three issues.

- The development of a patient centered process prototype to allow the direct generation and the return of clinical trials data to study participants by ensuring its sustainability and **foster the harmonization of the legal/ethical framework applicable to CT research in different European Member States**.

- **By putting the study participants at the very core of their data portability and secondary use** the FACILITATE project will make it easier to integrate both local and pan-European implementations considering best practices and data protection regulations.

- **Create adequate governance**

When talking about the secondary use of clinical trial data for future research we MUST explore the post-trial constraints in the EU and what are our responsibilities to allow continued access and use after trial closure.

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FACILITATE's DRIVING FORCE for CHANGE: Striking a balance

Road to comprehensive governance

How to reconcile opposing views

Flow	Logic implementation of consecutive steps
Fairness	Respect for patient and participants perspectives
Accountability	Co-creation
Data ownership – personal / public / private	**Alignment**
Need access to enough "good quality data"	**Inclusion of new technologies**

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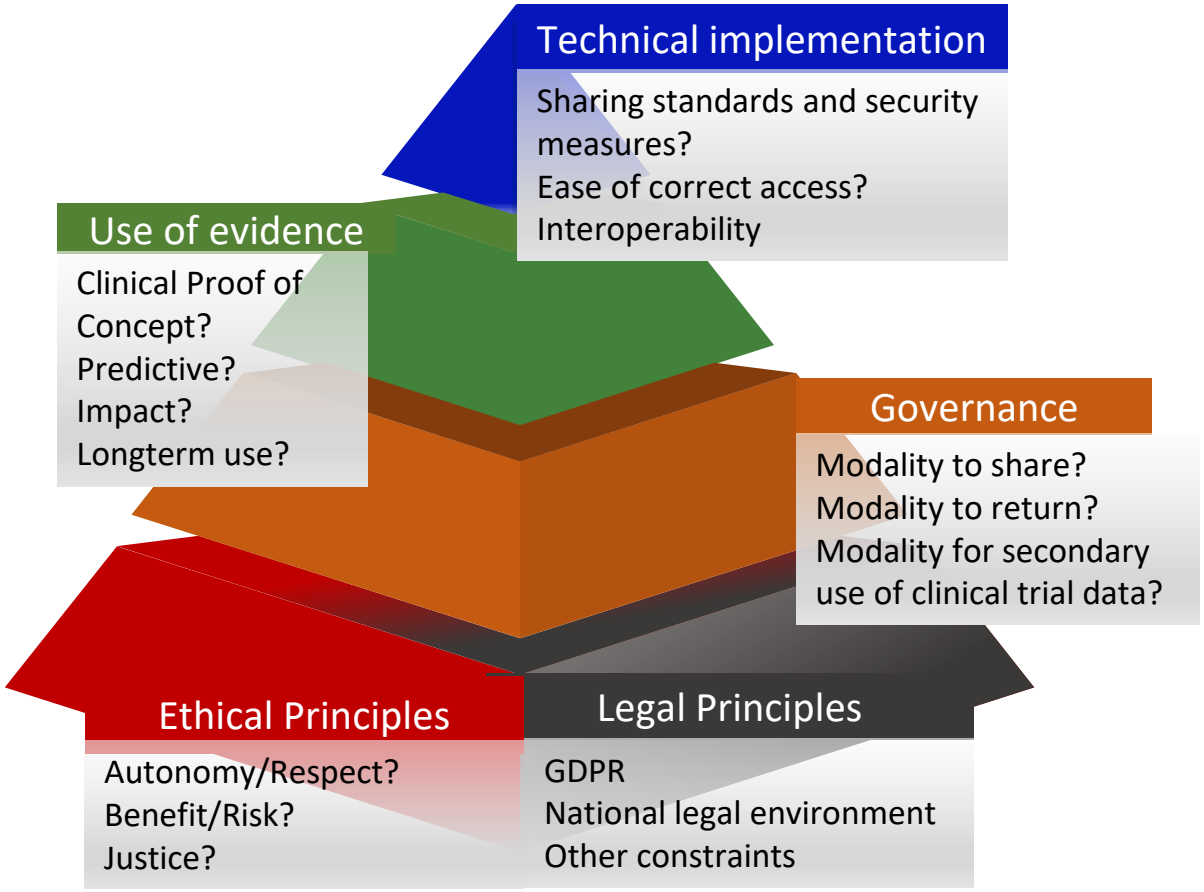
Architecture of the project



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Architecture of the project

Workpackage 3
Ethics, standardization and regulatory framework

Workpackage 4
Platform architecture design and requirements

Workpackage 1
Project management

Workpackage 5
Technology framework and interoperability solutions

Workpackage 2
Legal and Data Privacy framework

Workpage 6
Stakeholder engagement, Communication and Dissemination

Workpackage 7
Business exploitation and sustainability

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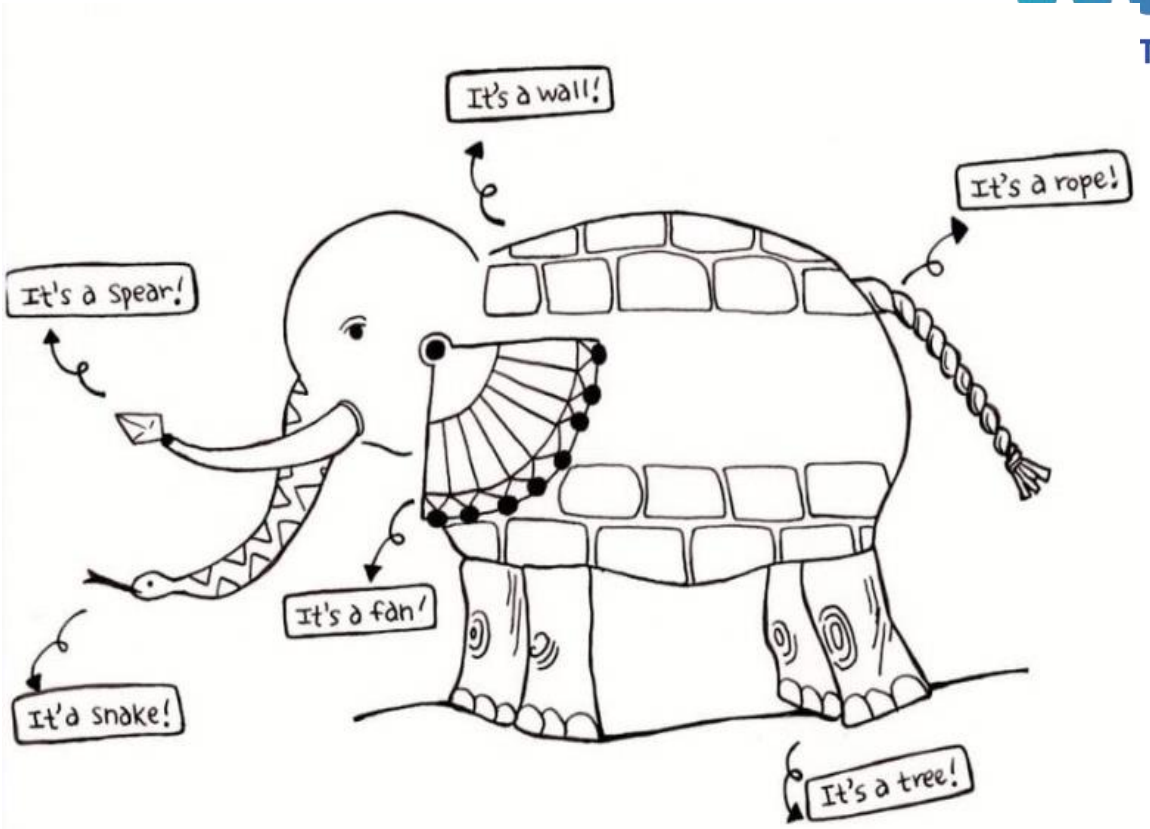
It’s not easy to say elephant



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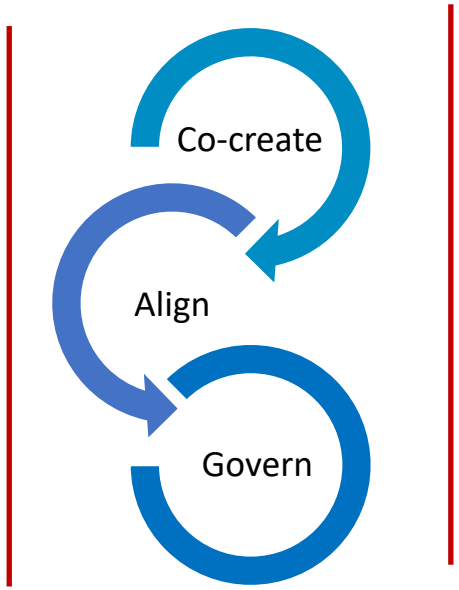
FACILITATE's DRIVING FORCE for CHANGE: Striking a balance

Road to comprehensive governance



Anticipate change	Critically assess how change will affect trust and data governance
Co-creation	Respect for patient and participants perspectives
Accountability	Safeguards and adequate security measures
Validity	If governance rules are no longer adequate verify possible valid alternatives
Adapt	**Adapt new rules to fit needs in a dynamic flexible way**

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Striking a Balance: Good Governance

Legal and ethical constraints

developing legal and ethical solutions that prioritize patient-centricity, privacy, and autonomy

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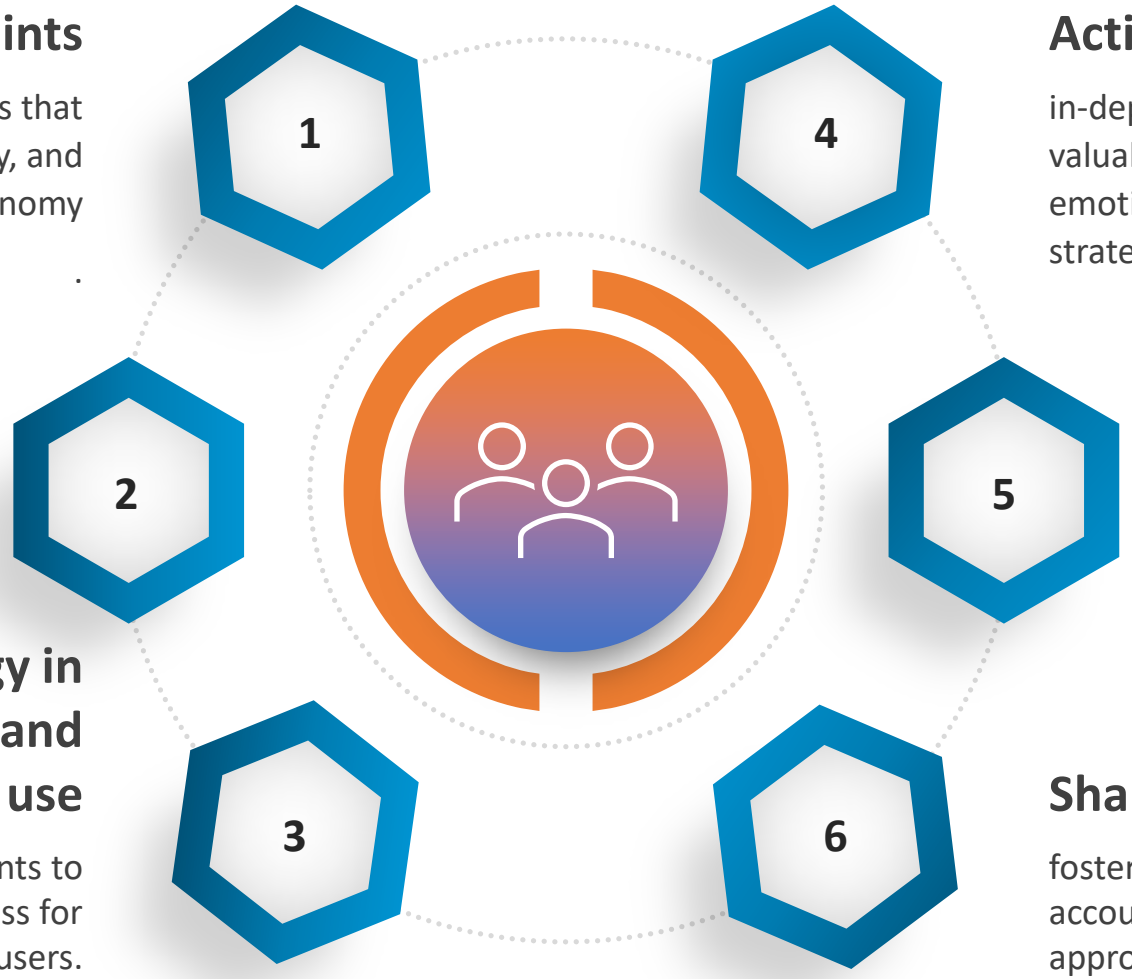
Regulatory Frameworks for Data Sharing and Reuse

examining the strengths and weaknesses of current regulatory frameworks,.

Role of technology in facilitating sharing and secondary use

leveraging technological advancements to ensure data protection and ease of access for authorized users.



Active patient engagement

in-depth conversations with patients provide valuable insights into their disease journey, emotional struggles, and successful coping strategies

Collaborative efforts

stakeholders must work together to create a framework that allows for the safe and ethical return and reuse of clinical trial data for research purposes, focusing on trust, accountability, and patient empowerment

Shared sense of purpose

fostering trust and collaboration, emphasizing accountability, and promoting patient-centric approaches in clinical research

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Striking a Balance: Good Governance

Accountability
Those who make decisions are responsible for them

Fair and inclusive
The interest of all stakeholders should be considered when implementing data return and secondary use processes

Transparency
The decision making process should be clear to all participants and partners

Based on TRUST
stakeholders must work together to create a framework that allows for the safe and ethical return and reuse of clinical trial data for research purposes, focusing on trust, accountability, and patient empowerment

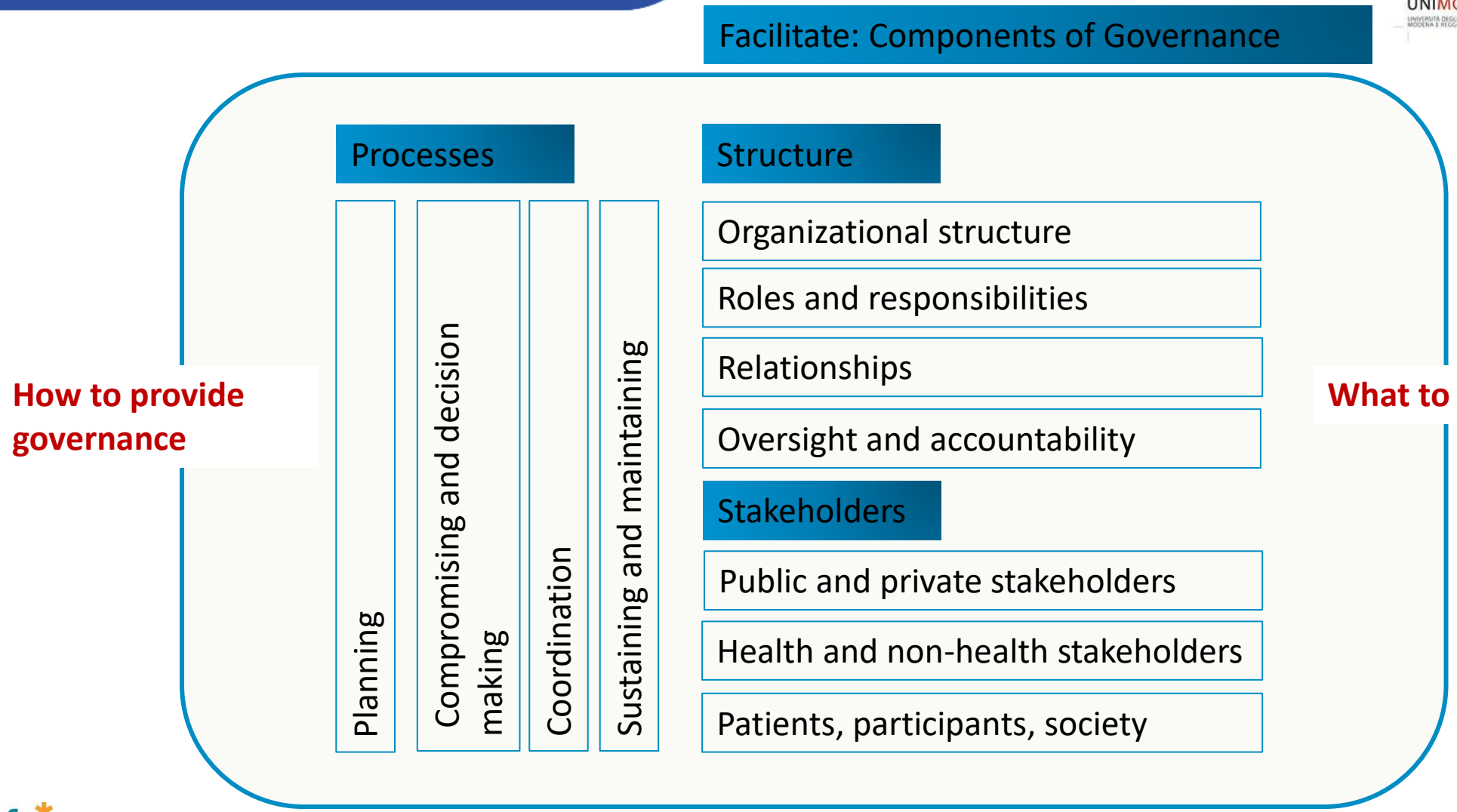
Legal alignment
Decisions should be in line with local law and legislation and are not arbitrary

Etical framework
Reciprocal and participatory
Protection of rights

Flexible and adaptive
Should be able to balance stakeholder and context different needs which may change over time.

Confidential
Data flows are managed in compliance with national and international practice to ensure patients safety and the secure management of data

DATA governance in FACILITATE



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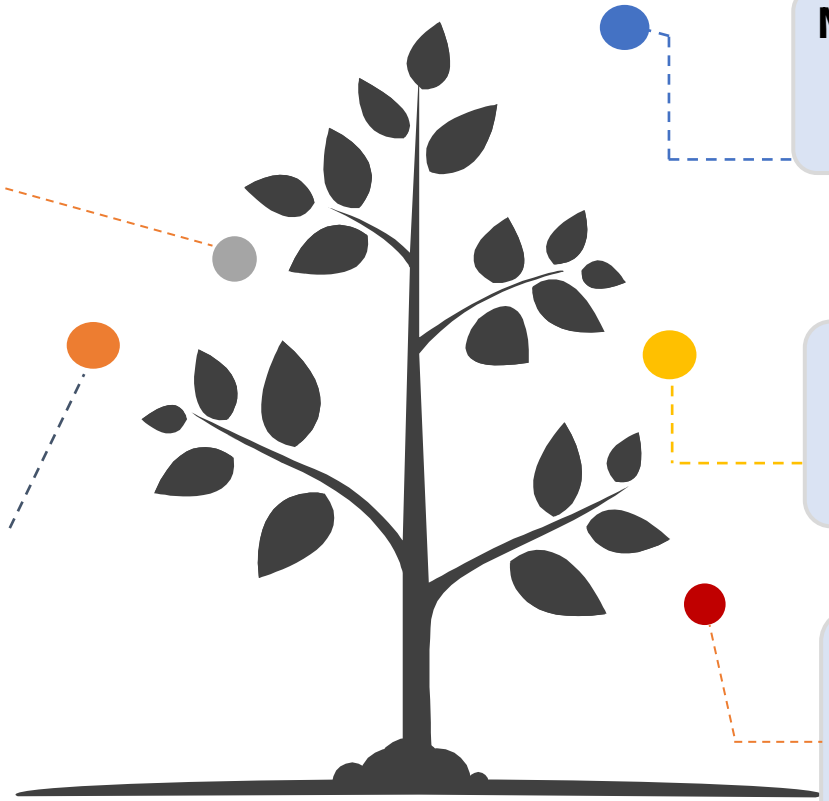
Adapted from WHO toolkit on governance

A complex & rich environment

Existing related initiatives
- EHDS
- Transcelerate
- MRTC

Stakeholders
- Bringing various angles
- Patients as corner stone
- Governance / Roles & Responsibilities

Regulations and regulators
- Privacy
- GDPR
- CTR
- FDA
- EMA



Methodology
- Scientific Integrity

Healthcare
- Real World Data
- EHR

Technology & Research
- Moving area (AI,
- deep learning…)

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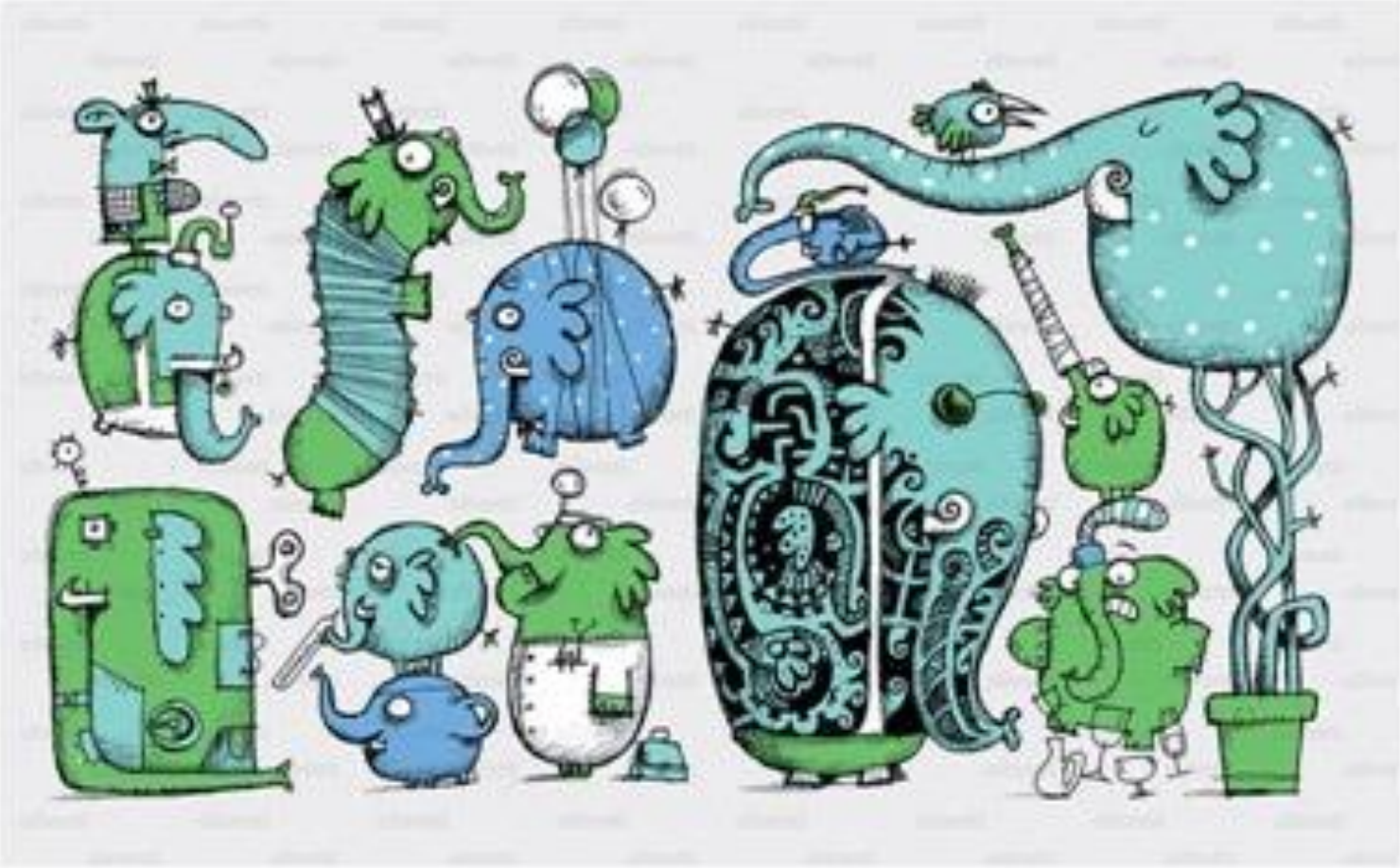

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