
FACILITATE
April 19, 2024
02:00PM-03:30PM CET
Let's FACILITATE Public Webinar
Maximizing the societal benefit
and lasting impact of clinical trials

# THE PANEL

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# Logistic of the webinar

- All participants will be muted for this call
- Audio: Connect to audio to listen to presentations via your computer or phone
- The preferred browser for the webinar is Chrome
- To submit a question to the presenters, type your question in the CHAT panel

The webinar is recorded in whole part

# Enabling Personalized Options to Improve Patient & Care Provider Experiences & Outcomes
# In the Research & Development of safe, effective, high quality, Innovative medicines for all patients


*Jean Sposaro, B.Sc. Masters of Science in Jurisprudence Healthcare, Pharmaceutical Law, Bioethics & Policy*

Global Drug Development

Global Clinical Trial Industry Collaborations at **Bristol-Myers Squibb**

**BMS:** EFPIA Lead : **IMI FACILITATE WP3 - WP6**

Past Individual Participant Data Return Initiative Lead at **TransCelerate**


***Human Advocate: empowering patients, building partnerships for Health Equity, Inclusion, Access to Health Data and Informed Shared Decision Making***

# FACILITATE

Placing the patient at the core of all intersecting disciplines, with our joint purpose dedicated to:

1) **Improve study participants access to their individual health data generated during the study, if they chose to receive it** and

2) Conduct a landscape assessment regarding the **(re) use of clinical trial data and its potential impact on scientific innovation and health equity**

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 : Striking a balance

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## 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

## 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

## Ethical 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



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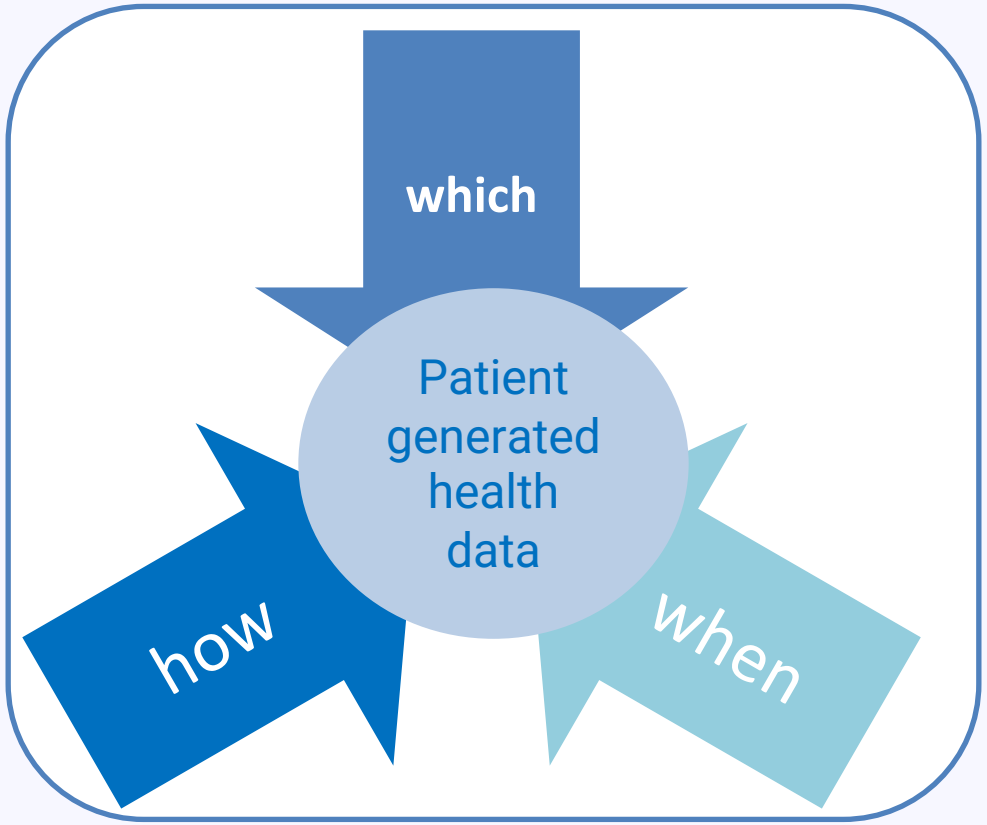
# FACILITATE purpose

## Individual Participant Data Return :What it is and What it is Not

- Addresses the concepts of **reciprocity, fairness and humility** by providing study participant meaningful options
- Ensures **compliance with GDPR, EHDS and ICH GCP**
- *NOT YET*, required by Regulation
- Independent of Aggregate Lay Summary Results
- Enables **Proactive** Possibilities

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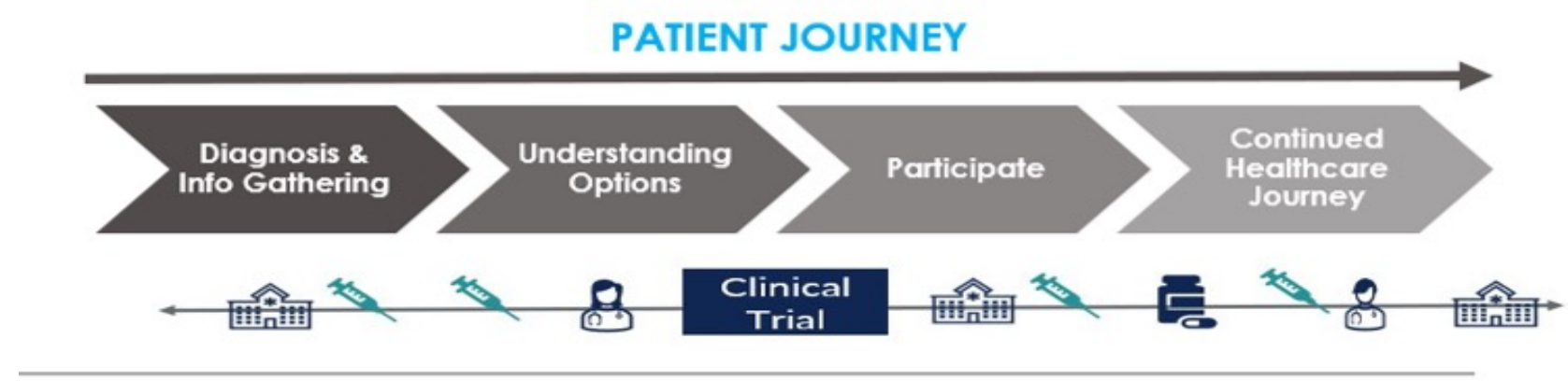
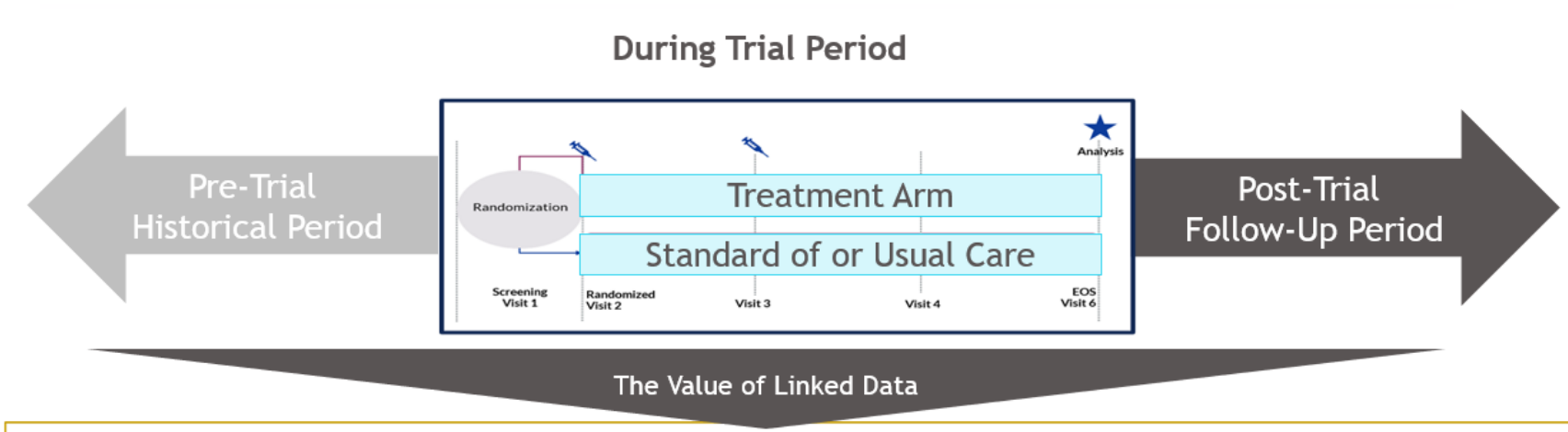
# WHY ITS IMPORTANT:
# MAXIMIZING SOCIETAL IMPACT ACROSS THE PATIENT JOURNEY




**The Value of Linked Data**

- Real-word HCRU pre-intervention
- Disease natural history
- Standard of care
- Treatment patterns pre-intervention
- Consolidated approach to patient consent, site engagement
- Supplement data capture between visits
- Contextualize adverse events
- Real-word HCRU post-intervention
- Long-term drug safety/effectiveness assessments
- Address data gaps for 'lost-to-follow-up' patients
- Label expansion

# WORKING TOGETHER WE CAN DO MORE TO CHANGE CULTURE AND IMPROVE UNDERSTANDNG

| | |
|---|---|
| TransCelerate BIOPHARMA INC. | Participant Data Return Initiative |
| MRCT MULTI-REGIONAL CLINICAL TRIALS THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD | Return of Individual Results |
| innovative health initiative / FACILITATE | FACILITATE |
| Pfizer | Returning Clinical Data to Patients |

List not exhaustive. Please refer to the TransCelerate's Participant Data Return Resource Pack for more information.

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# RETURN OF INDIVIDUAL CLINICAL TRIAL DATA

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## IMPORTANCE OF THE RETURN OF INDIVIDUAL CLINICAL TRIAL DATA

Participants in research studies consistently express a desire to receive both **personal and collective** research data from their involvement in studies.

**Societal expectations** regarding data transparency and ownership are changing, and **the practice of returning individual CT data aligns with and addresses these evolving expectations**.

**Core ethical principles in research are applicable and essential** in guiding the responsible return of individual research results to study participants.

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# Striking a Balance: Good Governance

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## Legal and ethical constraints

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

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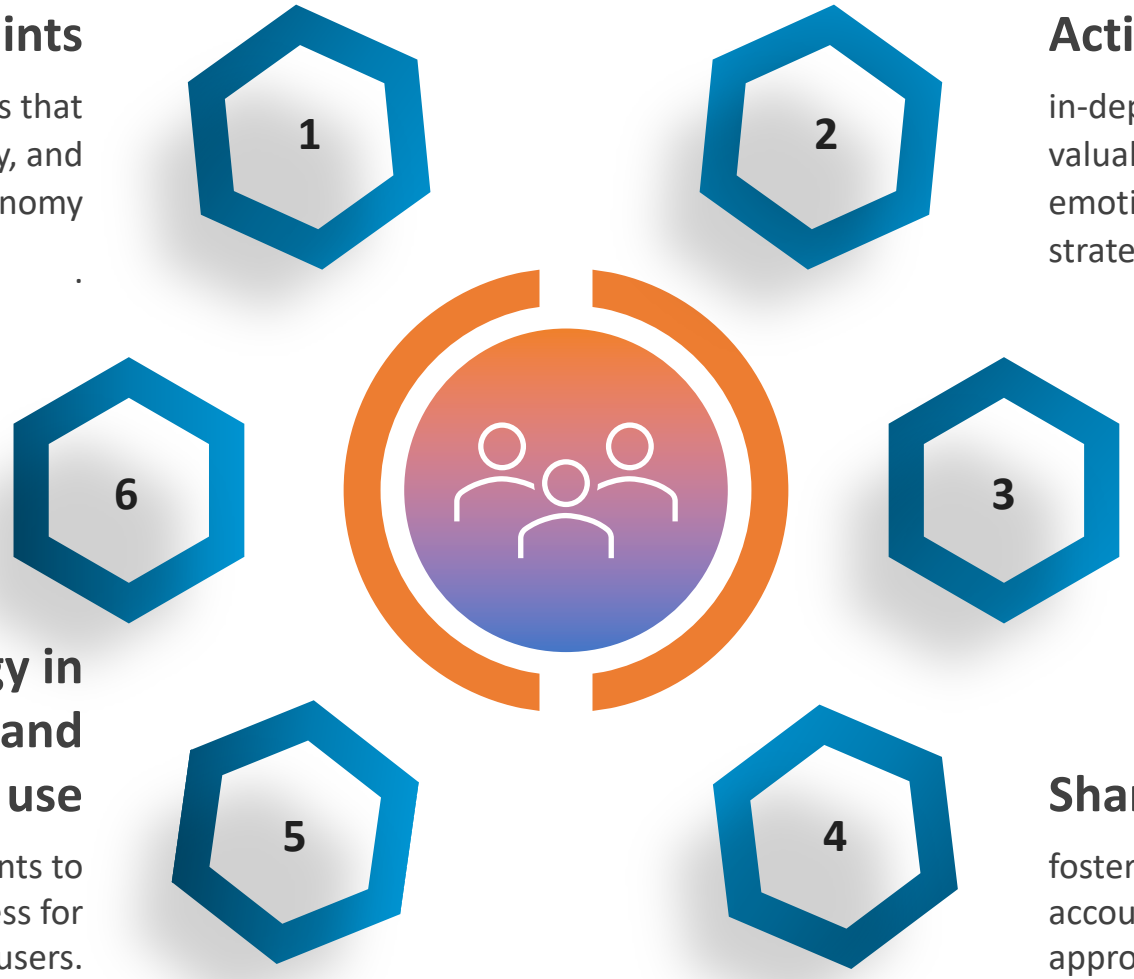
## Regulatory Frameworks for Data Sharing and Reuse

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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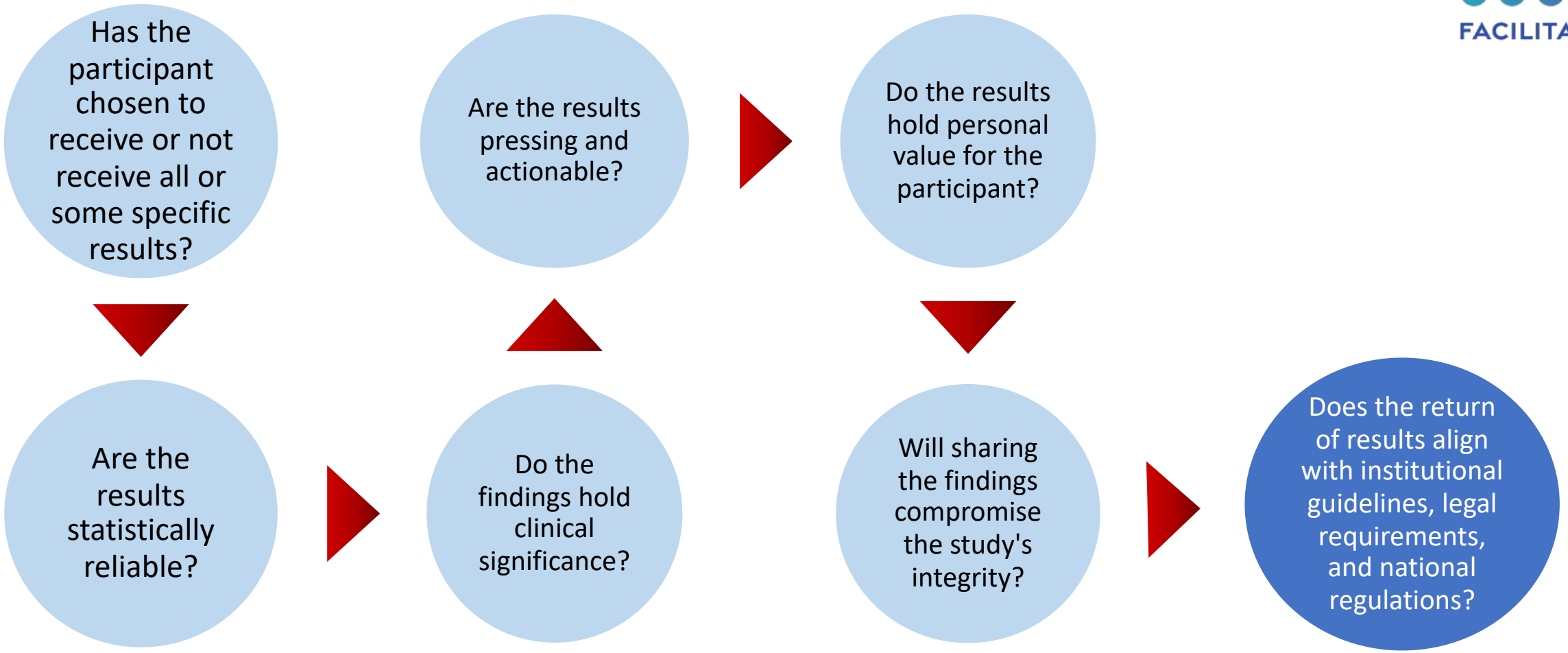
## *What* results should be shared?

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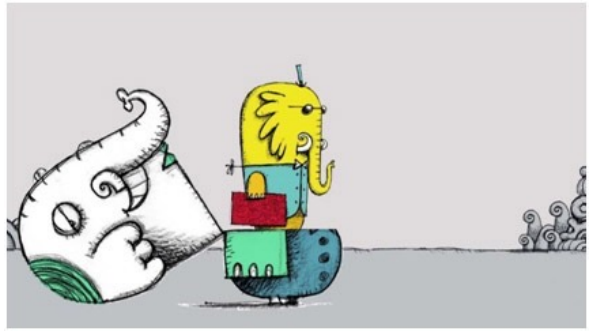
# GOVERNANCE driving CHANGE



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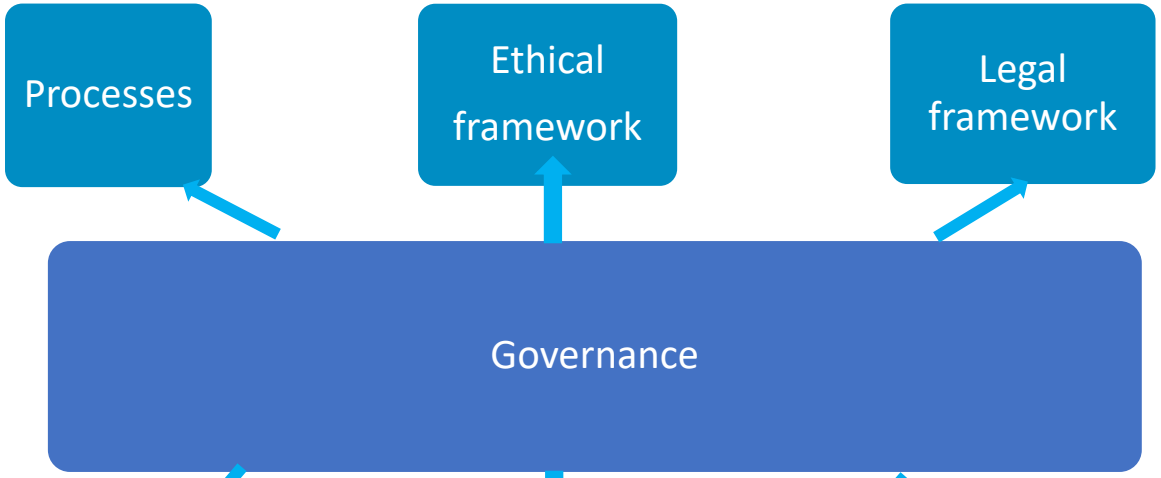
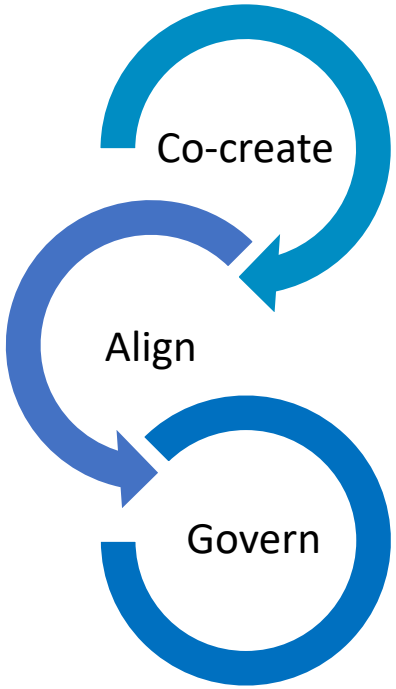
## How to provide governance




## What to govern

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# Trust in Clinical Trial Data Return

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- **Trust as a cornerstone of successful collaboration** and innovation in clinical trials
- **Solidarity-based approach:** recognizing and appreciating the long-term relationships between stakeholders (researchers, participants, sponsors, regulators)
- **Reciprocity-based relational autonomy**: acknowledging the interconnectedness and interdependence of all parties involved in clinical trials
- **Mutual collective accountability**: engaging patients as key informants, empowering them to be agents of change, and promoting shared responsibility in decision-making

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# Thank you for your attention

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# THANK YOU!