Big (RealWorld) Data:
Can pharma companies and academia be aligned?

Thursday June 16th

Prepared for the OECI 2022 Oncology Days, Valencia

Big (RW) data: may pharma companies and academia be aligned?

Promise of Real World data:

Accurately reflect the reality of clinical care

Tool for evaluation: real-world outcomes (safety, benefit)

Reduced biases – increased patient diversity
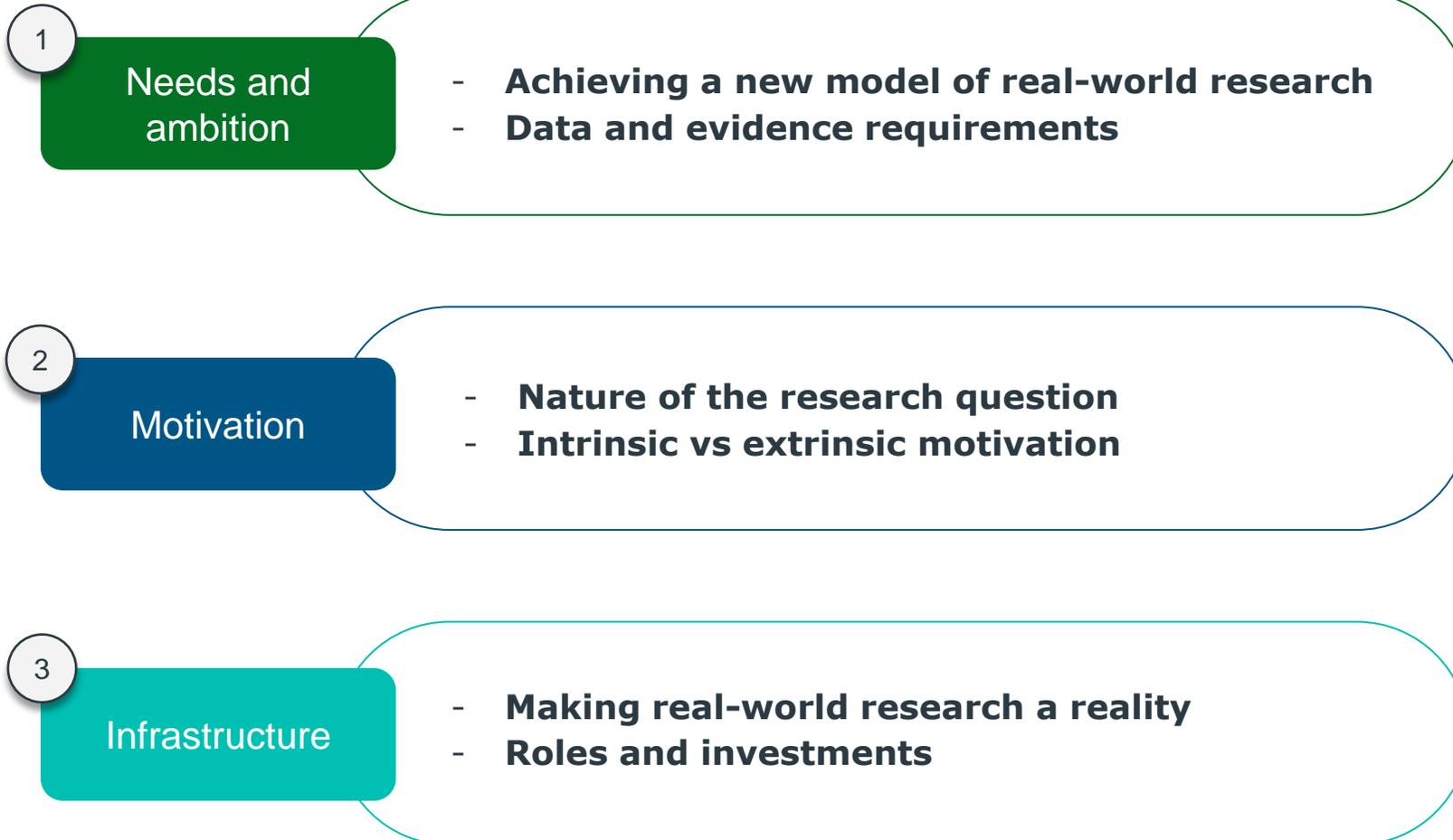
Challenges:

Achieving the required data quality

Scale of collaboration: cancer as a rare disease

Breadth of data (pathway completeness, e.g. orals)

Longitudinally and cross-institution pathways

Research execution (CDMs, IG, Ops, FedAnalytics)

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Three thoughts on pharmaco/academic alignment

1

Needs and ambition

- Achieving a new model of real-world research
- Data and evidence requirements

2

Motivation

- Nature of the research question
- Intrinsic vs extrinsic motivation

3

Infrastructure

- Making real-world research a reality
- Roles and investments

Needs and ambition

Needs and ambition	- **Achieving new model of real-world research** - **Data requirements**

i	Next generation RWE execution: efficiency, automation, speed, quality, population diversity
ii	Dimensionality of the data, breadth of treatment modalities; imaging, genomics
iii	Scale: intra and inter-country collaboration, achieving sufficient cohort sizes
iv	Longitudinally, including via patient-centricity

2: Motivations

2

Motivation

- **Nature of the research question**
- **Intrinsic vs extrinsic motivation**

Pharmaco: maximizing appropriate and high-value use of the asset

Connection to a commercial asset and the zone of research interest

Collaboration: motivated engagement for indirect research topics

New models of healthcare engagement, changes in Pharmaco 'customer model'

Financing the research activity

3: Building the required European infrastructure

Infrastructure

- **Making real-world research a reality**
- **Roles and investments**

Everyone wants to buy a train ticket… [very] few people want to lay the tracks and build the trains…

Railways and Real-world Infrastructure…
Vertical Separation not Horizontal Integration?

1

Track

Builds, maintains, repairs

Very high capital outlay, stable, organic low-margin business model, Regulator control (Price/Quality)

Some

Operator

Passenger Services, journeys, tickets

Low capital outlay, quality-driven competition, variable demand, mid/high margin model

Few

Trains

Builds, maintains, repairs

High capital outlay, quality driven competition, stable mid-margin model

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Railways and Real-world Infrastructure…
Vertical Separation not Horizontal Integration?

1 **Track**

Builds, maintains, repairs

Very high capital outlay, stable, organic low-margin business model, Regulator control (Price/Quality)

1 **RWE Infra Architecture**

Standards: ontologies, RDM, general consent models, OS tech, SAMD

Some **Operator**

Passenger Services, journeys, tickets

Low capital outlay, quality-driven competition, variable demand, mid/high margin model

Many **Hospitals, other sites**

Data Controllership, ongoing data operations, site-specific context

Some **Research Services**

Protocol Development, epi expertise, StAP, Federated Analytics

Few **Trains**

Builds, maintains, repairs

High capital outlay, quality driven competition, stable mid-margin model

To catalyse the achievement of a new model of Real-World research, do we need a 'vertical separation' model?

Summary

1 Needs and ambition
- **Achieving new model of real-world research**
- **Data requirements**

Aligned and allied

2 Motivation
- **Nature of the research question**
- **Intrinsic vs extrinsic motivation**

Tricky…

3 Infrastructure
- **Making real-world research a reality**
- **Roles and investments**

Aligned and allied, but who acts?