

IHI Call Days | Call 9

● *Enhancing EU Competitiveness by
Integrating Pragmatic Trials and Real-
World Evidence in Precision Oncology*

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Why focus on digitisation of pragmatic precision oncology trials and RWE?

The challenges in precision oncology trials

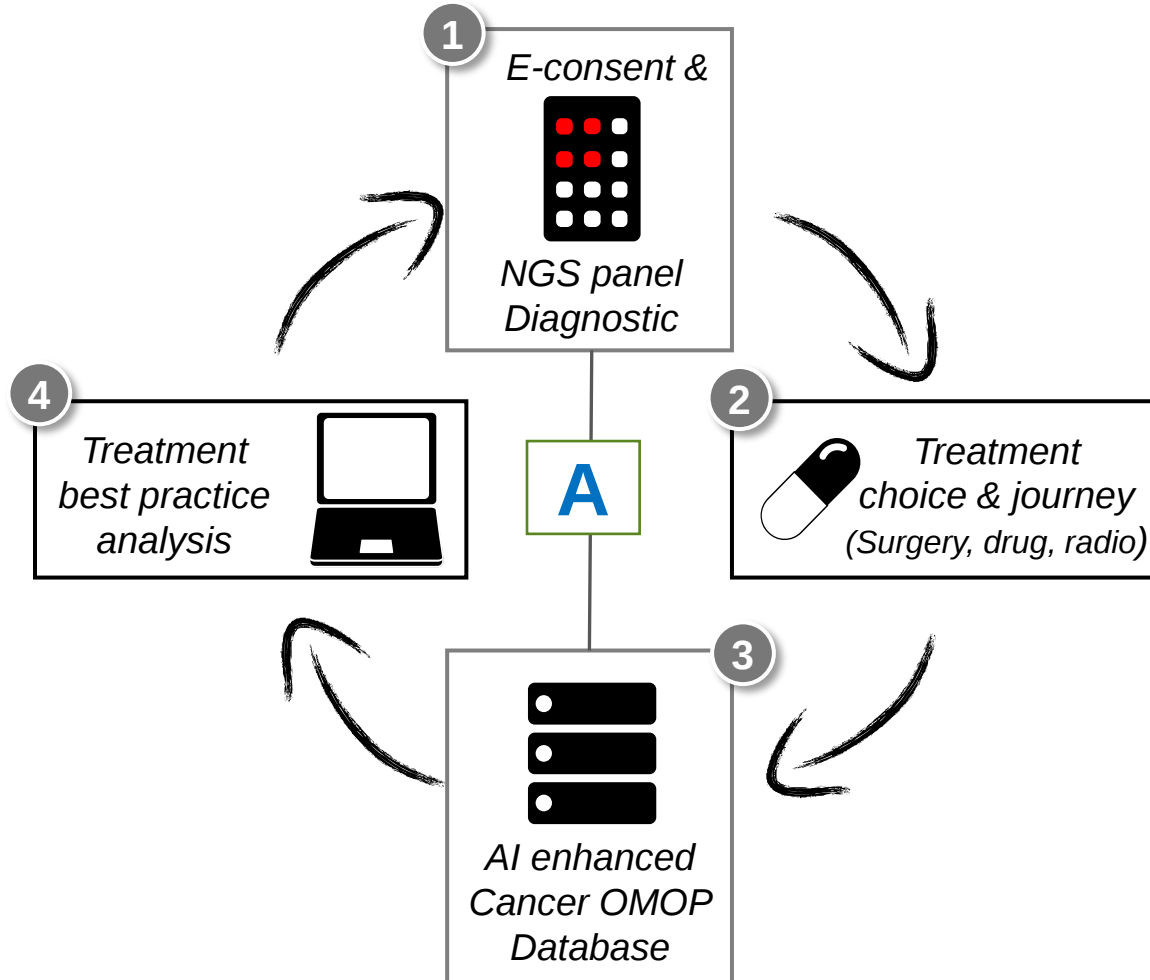
- **Patient recruitment:** target mutations are rare, I/E complex, a “needle in a haystack” problem
- **Regulatory & GDPR complexity:** set-up times for European trials are slow vs key peers; digital screening challenging given privacy
- **Imaging data collection costs:** radiological outcomes like Overall Response are expensive
- **Uncertain real world value:** the super-fit patient and proxy endpoint problem for payers

IHI objectives & key public benefits

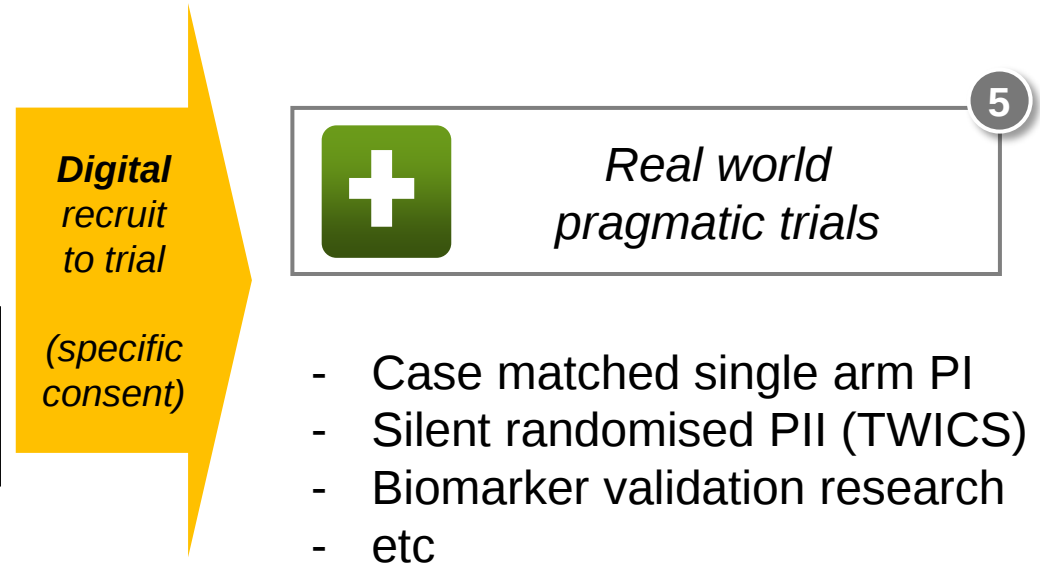
- **SO4:** *exploit the full potential of digitalisation and data exchange*
- **Benefits to patients:** *trials as extension of care bring valuable treatment options*
- **Benefit to health systems:** *build a learning health system for precision oncology and reduce variation in outcomes*
- **Benefit to taxpayers:** *make Europe globally attractive for oncology trials (jobs, foreign direct investment etc)*

Approach: a digital, federated care quality precision oncology registry with pragmatic trials run inside

A An enhanced version of DigiONE, our federated Cancer OMOP clinical registry



B Next generation pragmatic trials, developed from PRIME-ROSE



Why IHI? This is a fundamentally cross-sector solution needing industry to scale

- **Pharmaceutical companies & academic trialists:** co-design of next-indication pragmatic trials; targeted drugs access; 1st proof of concepts
- **Molecular diagnostic majors & Cancer OMOP experts:** integration of new Cancer OMOP bioinformatics solutions into routine NGS workflows
- **Imaging companies & academic AI experts:** developing open-source radiographic outcome assessment AI for rapid adoption
- **National informatics initiatives:** align on pragmatic registry solutions and tailoring nationally appropriate, scalable international informatics solutions
- **Patient groups & regulators:** ensure that design trade-offs prioritise citizen-centric outcomes and address health equity needs

Outcomes and Impact

Outcomes

- Showcase Europe-wide **digital precision oncology trial screening**
- **Develop globally competitive next-indication precision pragmatic trial solutions**
- **Automate radiographic outcomes:** make it cheap enough to RECIST every patient
- **Develop scalable, hospital based federated registry solutions** to demonstrate long term treatment benefits and reduce variation in care

Impact

- *Step change in the **attractiveness of Europe for large scale pharma trials** given improved speed, cost and scale*
- ***Stop just measuring outcome variation and start managing it digitally***

Expertise and resources

- **We have** the academic side 60% covered:
 - Multiple national cancer informatics consortia
 - Multiple pragmatic trial consortia
 - Proof of concept on key technology elements over 6 countries
 - Network of Europe wide pragmatic trial ready hospitals (**more welcome** with OMOP experience)
- We are **looking for** the industry side:
 - IKOP / IKAA from **EFPIA members on pragmatic trials** (Drugs, design, stats, methods, reg.)
 - IKOP / IKAA from **Medtech Europe members for molecular DX bioinformatics** (NGS => new Cancer OMOP tables)
 - IKOP / IKIA from **COCIR members for imaging AI, NLP and OMOP SI expertise** to drive RECIST automation AI and hospital OMOP conversions to DigiONE standard

* IKOP - in-kind contributions to operational activities

** IKAA - in-kind contribution to additional activities