IDEAL4RWE – the RWE Training Programme in DIGICORE

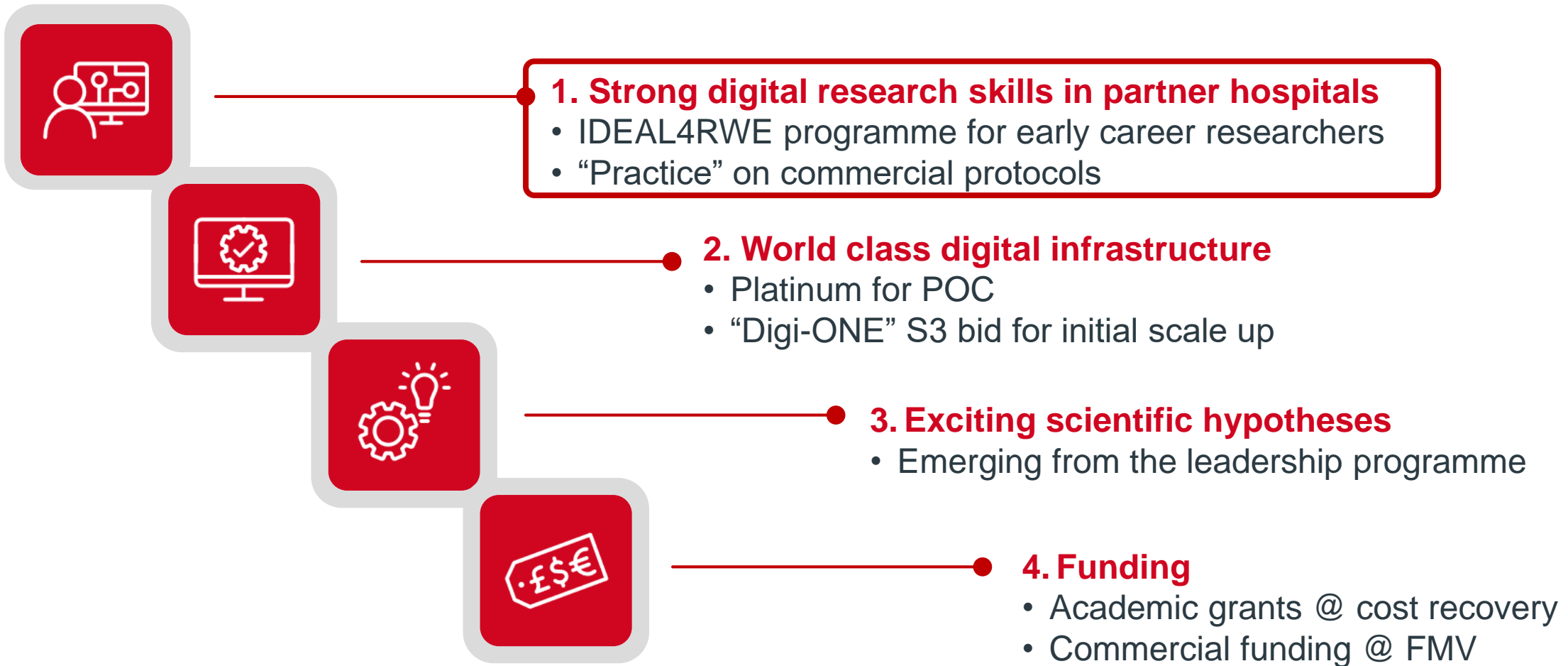*Iwona Ługowska and James Anderson*

November 13, 2023

Objectives for today

	(Re-) introduction to IDEAL4RWE	**10 mins**
	Study team presentations	**30 mins**
	Reflections and lessons learned	**10 mins**
	Next steps – announcing a new training programme	**10 mins**

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What does it take for DIGICORE to succeed in its mission?

1. Strong digital research skills in partner hospitals
- IDEAL4RWE programme for early career researchers
- "Practice" on commercial protocols

2. World class digital infrastructure
- Platinum for POC
- "Digi-ONE" S3 bid for initial scale up

3. Exciting scientific hypotheses
- Emerging from the leadership programme

4. Funding
- Academic grants @ cost recovery
- Commercial funding @ FMV

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IDEAL4RWE is a first-of-its kind skills and leadership development programme

Training

Team activity

| Recruitment | Basic training and team formation – light | Advanced training & protocol – intensive |

Jan-Apr 2022

Awareness building and recruitment:
- **Centres**
- **Direct to potential participants**

150+ centres invited

Apr-May 2022

101 RWE basics

Teams form

0 *Individuals sign to learn more*

Team "dating"

May-Jul 2022

102 Application training

Teams develop simple RWE study concepts

1 *Short team application*

c.50 applicants from 30 centres join training

Jul 2022- Q3 2023

103 Leadership training

201 Advanced RWE technical training

Teams refine and drive pilot RWE programmes with PoC study funding from IQVIA

2 *Protocol & Data model*

3 *Poster & Output*

25 individuals selected for leadership training
4 studies / teams (3 funded) from 20 centres

We are here ▲

Mobilisation

Proof of concept study output for follow-on funds

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3

This has been a substantial programme, and feedback has been excellent

The story in numbers

- **47 participants** signed up for phase 1

- **4 seminars** delivered on RWE technical content

- **4 teams** self-organised and working on studies

- **3 teams** awarded **€210k funding** by IQVIA (LAB decision)

- **2 "leadership retreats"** in Paris (Sept '22) and Frankfurt (March '23)

- **2** conference abstracts submitted

- Overall **feedback** received
  - "How likely to recommend?" **8.8/10**
  - "Net promoter score" **62%**

> *…a real opportunity to foster skills we are not used to using in daily practice*
> **Clinician**

> *I'm very impressed with the programme… I have learned a lot about myself and how I relate to others in meetings and my work environment*
> **Data Scientist**

> *the topics [covered]…made it possible to think critically through our own project/process*
> **Clinician**

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We are grateful for the input and collaboration of our leadership advisory board

Prof David Cameron
(Edinburgh University) – Co-chair

Prof Iwona Lugowska
(Oncology Institute, Poland) – Co-chair

Prof Massimo di Maio
(Oncology Department, Turin)

Prof Janne Vehreschild
(German Centre for Infection Research)

Dr Sue Cheeseman
(Leeds Teaching Hospital)

Dr Anne-Sophie Hamy-Petit
(University of Paris)

Prof Andre Dekker
(Maastricht Comprehensive Cancer Centre)

Gilliosa Spurrier Bernard
(Co-chair WECAN)

Dr Mariana Guergova-Kuras
(IQVIA)

James Anderson
(DIGICORE)

TEAM PRESENTATIONS

Breast

TEAM PRESENTATIONS

Head and Neck

TEAM PRESENTATIONS

Prostate

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What we learned: planned vs. actual patient numbers

Indication (team size)	Planned countries represented					Planned # patients	Actual countries represented						Actual # patients
Breast	BE	IT	UK	FR	CZ	780	BE	IT	UK	FR	CZ		532 ↓
	Poland	Portugal	Slovenia				Poland	Portugal	Slovenia				
Head and neck	Slovenia	Portugal	Norway	IT	Spain	530	Slovenia	Portugal	Norway	IT	Spain	Poland	272 ↓
Prostate	NL	DK	Spain	FR	UK	IT	1,010	NL	DK	Spain	FR	UK	IT	554 ↓
Colorectal	CZ	IT	Croatia	Poland		980	IT	Croatia	Portugal				~550 (TBC) ↓

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Q&A

? **Questions for the teams, the organisers or the Leadership Advisory Board**

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Summary of key lessons learned through process

RWD CDM should be kept as simple as possible

A test run of data extraction even before the protocol completion

Obtain clear perspective and sign-off from data guardians

Genuine collaboration takes work

Leadership, decision-making and dispute-resolving approach

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Announcement: 2 training programmes to support i3

1

MEDOC/ ETL training

To upskill <u>hospital IT staff and data scientists</u> to extract and configure data to MEDOC OMOP standard for cancer studies

2

IDEAL4OMOP

To give <u>early career researchers (clinical and non-clinical)</u> the skills they need to design and run cancer OMOP studies

Funding from i3 award budget, with additional contributions from IQVIA

1) MEDOC/ ETL training scope and approach

Who?	• **C. 30 Hospital IT staff and data scientists** • **SQL familiarity** (but OMOP not needed) – could be clinician with coding skills or high-performing IT team member
What?	• Training on **basics of OMOP and MEDOC** • Light-touch support in **building a cancer OMOP instance** in their hospital
How?	• **Virtual seminars basics of OMOP/ MEDOC** (Q1-2, 2024) • **In-person training event** (aligned w/ OHDSI 2024 tbc) • Light touch **peer-peer support**
When?	• **Q1 2024** (recruitment) • **Q2 2024** (seminars/ training) • **Q3-Q4 2024** (light touch support)
T&Cs?	• **i3 hospital** (travel funded by grant) • **Other organisations** (need to fund travel)

Aims

By July 2024:

• **A cohort of 30+ OMOP trained hospital IT staff,** leading in-hospital implementation

• **A library of open source tools/ documentation** for use by other hospitals (built off existing implementation guide)

By end 2024 and beyond:

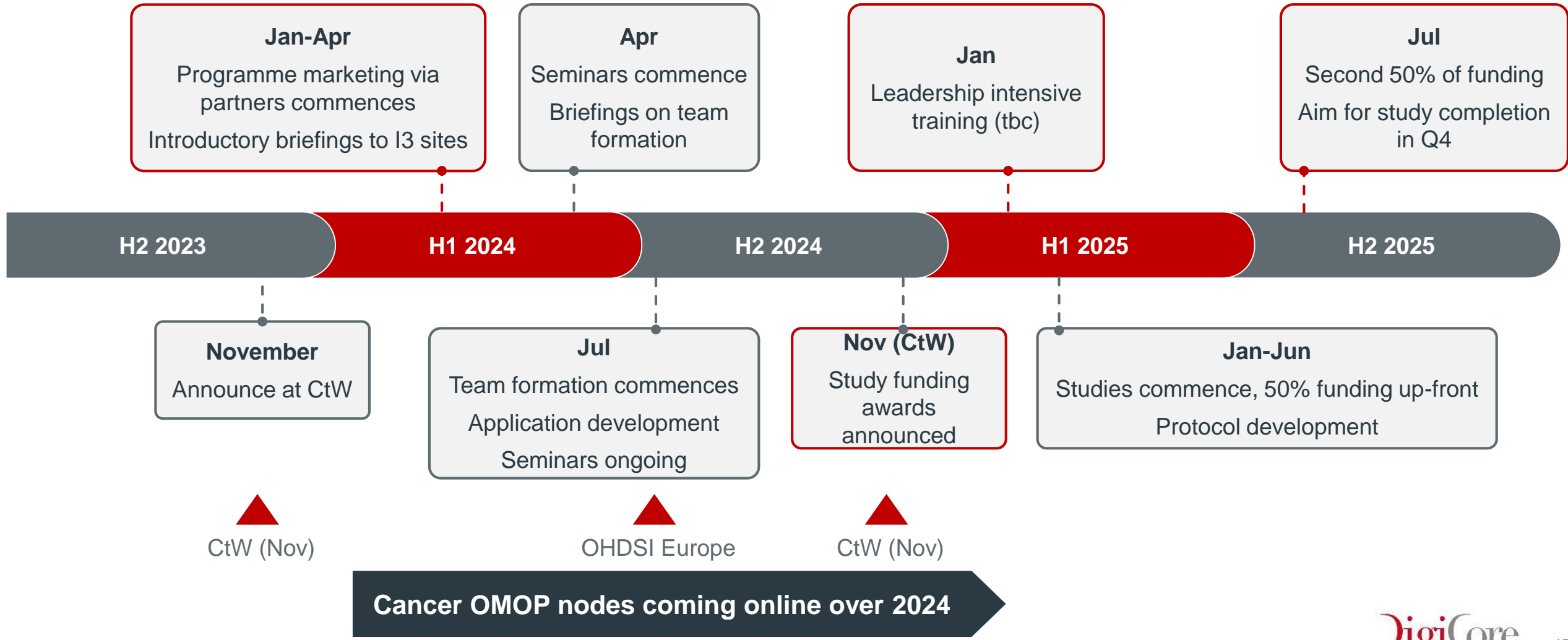• **Expanded** number of DIGICORE members with basic OMOP instance (suitable for e.g., counts)

2) IDEAL4OMOP scope and approach

Who?	• **Under 45yr** clinicians, data scientists etc. • Want to lead **OMOP enabled oncology research**	
What?	• Training on both **technical and leadership skills** • Delivery of an international **proof-of-concept study**	
How?	• **Mix of training styles:** Face-to-face and virtual • **Funding available** (can cover backfill) • **Advisory board oversight <u>and allocation of funding</u>**	
When?	• **Recruitment and free introductory programme** in Q1-2 2024 • **RWE studies start in Q4 2024, conclude Q4 2025**	
T&Cs?	• **Cancer OMOP instance** in place (or planned with funding) • For backfill study funding: **centre must be DIGICORE member.** Others can participate – but no funding • **Balance of different tumour types** (solid/ haem/ rare)	

Aims

By June 2025

• **A cohort of 30 future research leaders skilled in OMOP research**

• **c. 3 proof of concept studies delivering analytic outputs** (IQVIA provides study fund of €300k, tbc)

• **Increased awareness** of DIGICORE

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Indicative timeline for IDEAL4OMOP Cohort

Jan-Apr

Programme marketing via partners commences

Introductory briefings to I3 sites

Apr

Seminars commence

Briefings on team formation

Jan

Leadership intensive training (tbc)

Jul

Second 50% of funding

Aim for study completion in Q4

H2 2023	H1 2024	H2 2024	H1 2025	H2 2025

November

Announce at CtW

Jul

Team formation commences

Application development

Seminars ongoing

Nov (CtW)

Study funding awards announced

Jan-Jun

Studies commence, 50% funding up-front

Protocol development

CtW (Nov)

OHDSI Europe

CtW (Nov)

Cancer OMOP nodes coming online over 2024

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Target audience for IDEAL4OMOP, and what's in it for them?

Target clinician (statistician/ epi) is research interested (but not research obsessed)

% clinicians in Cancer centre X

Trialist

Research interested

Frontline care delivery

- Want to balance a career in care delivery & research
- Don't want the stress of trials (e.g. FDA reporting)

- Typically (but not always)
  - Younger, digital native
  - Care quality focused
  - Some research experience, but not lots

What is in it for them?

- Seed funding & training for pilot studies

- International peers in their disease (= HORIZON team ready)

- Deep methods expertise from partners

- Secretarial / coordination support

A unique opportunity to create large scale, <u>fundable</u> outcomes research consortia

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We need your help: We are starting recruitment now!

If you or colleagues are interested in learning more:

- Expressions of interest to training@digicore-cancer.eu

- Speak to a member of the DIGICORE team

- Look out for introductory seminars coming soon