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IDEAL4RWE

Introductory Seminar

April 19, 2022

The Digital Institute for Cancer Outcomes Research

Objectives for today

Introduce DIGICORE – The Digital Institute for Cancer Outcomes Research	**5 mins**
Outline the IDEAL4RWE leadership programme • Rationale • Benefits to you, and commitment expected	**10 mins**
Share a case example of an outcome study in ovarian cancer: • Outcomes and insights achieved • Lessons learned	**30 mins**
Next steps & Q+A • How to sign up for the full programme • What you need to do before the summer	**15 mins**

Introducing speakers

James Anderson

Leadership Development Advisor, DIGICORE

Professor Geoff Hall

Chief Clinical Informatics Officer, Leeds, and ORWIC study lead

Mariana Guergova-Kuras

IQVIA Country Lead, France, for Oncology Evidence Network

Will Sopwith

RWE Advisor, DIGICORE

Piers Mahon

Commercial Research Manager, DIGICORE

DIGICORE is a new collaboration that aims to transform and digitise cancer outcome research in Europe

Founding organisations

Cancer Networks

unicancer

ALLIANCE AGAINST CANCER

Industry

IQVIA

illumina

Member centres

Membership open to all European cancer centres

Sister cancer network OECI Organisation of European Cancer Institutes

DIGital Institute for Cancer Outcomes Research (DIGICORE)

Pan-EU research collaboration to study cancer outcomes, capitalizing on increase in **precision oncology**

Independent European Economic Interest Group (like OECI) with 30 cancer centres today

Benefits and rationale

- For **Cancer Centres**, pool cancer data across sites for improved translational research
- For **Patients,** broader trial access and in future better outcomes
- **For IQVIA,** drive commercial multi – centre, international real world evidence projects in precision oncology and drive precision trial recruitment
- **For All** Grow clinical evidence base for molecular diagnostic tests in improving outcomes and accelerate reimbursement for all vendors

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Individual centre members of DIGICORE network in 16 countries

TAYS Cancer Centre
Vision Zero Cancer
Oslo University Hospital

Edinburgh
Trinity St James

Maastricht CCC
Saint Luc
UCC Frankfurt
IPO Porto
START Madrid

Institut Curie,
Centre Léon Bérard,
Centre Jean Perrin,
ICO

Tartu UH
Marie Skłodowska Curie
Masaryk Memorial
Inst of Oncology Ljubljana
Sestre Milosrdnice

IEO,
INT Milan,
Gemelli,
IRST,
Reggio Emilia,
San Matteo,
Humanitas Mirasole,
Istituti Fisioterapici Ospedalieri, San Raffaele,
IFOM,
INT Pascale

Real World Evidence (RWE) presents a huge opportunity for DIGICORE to transform outcomes research and improve patient care

RWE can improve patient care

- **Benchmarking outcomes and standard of care** across countries to identify potential care improvements
- Developing patient cohorts in **rare cancers**
- Linking clinical information to biomarkers to better understand **precision medicine**
- Using **external comparators** to complement single arm clinical trials
- Assessing use and value of **diagnostics**

Significant funds are coming available for digital infrastructure/RWE

Potential source of funding next 5 years	Total funding (estimate)	Of which digital infrastructure (estimate)
Recovery and resilience facility	€100bn	**€12bn***
Cancer mission	€2.6bn	**€0.1 to 0.2bn****
IHI + life sciences industry	€500bn	**€1.5 to 2bn*****

*Digital transition in healthcare funding estimates; **5 to 10% total; ***IHI and in-house research programme funding vs. global R&D spend in Cancer
Source: European Commission Recovery and Resilience Scoreboard, Dec 2021

To realise DIGICORE's vision we will need a new generation of outcome researchers to digitise cancer control

DIGICORE is investing in infrastructure: "A better digital microscope" for cancer outcomes research…

… but to use it well will need new research skills and leadership inside cancer centres

Solution

IQVIA – **D**IGICORE **E**arly **C**areer **L**eadership **P**rogramme for **R**eal **W**orld **E**vidence (IDEAL4RWE)

IDEAL4RWE will build these skills among emerging research leaders

Who?	• **Under 45,** clinicians, data scientists etc. Interested in **outcome research** and ambitious to lead digital revolution in RWE. Employed in **healthcare/not-for-profit** in **Europe**
What?	• Training on both **technical and leadership skills** for RWE • Based around delivery of an international **proof-of-concept** study
How?	• **Mix of training styles:** Face-to-face and virtual • Full programme **involves "test" application – funding available**
When?	• **Starts** in Q2 2022 – free "taster" programme • **RWE studies start in Q4 2022/Q1 2023** • **Concludes** H1 2023
T&Cs?	• Open to **multi-centre teams** of early career researchers • **Must have support of their centre** for some research time • Their centre must **join DIGICORE** • 80% study funds spent in centres contracted with IQVIA

Where we want to get to

By April 2023

- **A cohort of 20-25 future leaders (focus on clinicians but others involved)** trained through the whole programme – Training budgets of €150K + staff time
- **5-7 proof of concept studies** developed, with **3 delivering analytic outputs** (study fund of €210k)
- A plan for **future cohorts** from 2023 on

Part 1: Basic training and team formation (to July 2022)

Basic training and team formation

Apr-May 2022

101 RWE basics (2 seminars)

Basics of RWE and form teams

(From today) – course registration

Team formation starts

May-Jul 2022

102 Application training (2 seminars)

Teams develop simple RWE study concepts

Study concept and submission (July)

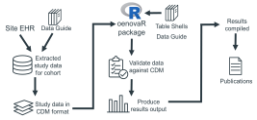
Training in outcomes study planning

Study overview

Patient cohort across 7 HCPs

HCP	Patent cohort
Site 1 - UK	515
Site 2 - France	698
Site 3 - Germany	139
Site 4 - France	466
Site 5 - Iberia	300
Site 6 – E. Europe	446
Site 7 - Asia	957
Total	**3,055**

Harmonized data analysis by local teams



Analysis performed in less than 4 weeks

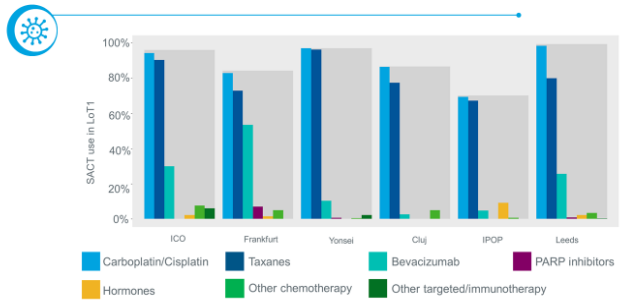
Study overview

- Epithelial ovarian cancer
  - Patient characteristics (e.g. histology, biomarkers, stage, breast cancer)
  - Genetic and molecular phenotype (germline, somatic BRCA, HRD)
  - Treatment patterns (surgery, lines of chemotherapy)
  - Outcomes from diagnosis & recurrence(s) to death

The Digital Institute for Cancer Outcomes Research

Training on relevant outcome case studies

Multi-centre study – Ovarian cancer – ORWIC – First-line therapy



Building a team to plan an outcomes study

- **TA:** p53 wild-type NSCLC
- **Objectives:** Natural history, treatment patterns and outcomes (2015-2020)
- **Patient cohort:** 1800 from 4 countries
- **Project milestones:** LPI, data curation, analysis, output

Part 2: Learning by doing (July 2022 to April 2023)

Advanced team-based training & protocol – Intensive

Jul 2022-Apr 2023

103 Leadership training/201 Advanced RWE technical training

Teams refine and drive pilot RWE programmes.
Selected teams (3-5) receive PoC study funding from IQVIA

Teams apply for funding

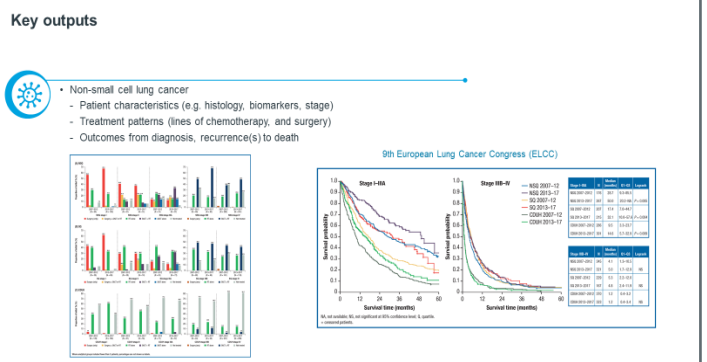
6-8 teams get intensive training

- **F2F Leadership Training**
- **Peer Learning Sets**
- **Optional 1:1 Coaching**
- **Advanced Technical Training**

Outcome study funding application

- Protocol
- Common data model
- Evidence of progress to date
- Up to €210k total for 3-4 studies
- Awarded by independent advisory board

3-4 teams get to output



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An expert panel of internationally renowned researchers will provide advice and allocate funding throughout the programme

Members of IDEAL4RWE Leadership Advisory Board (LAB)

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)

Setting you up for future success in real world research

The first cohort at the cutting edge of the digital revolution

What you get

New skills

- **Face-to-face** leadership development training (places limited)
- **6-8 virtual seminars** from leading researchers
- **Peer learning**
- **Coaching**

Potential **funding** for an outcome study (up to **€210k** for **3+** studies)

Network of like-minded collaborators and mentorship from **leading international** researchers

A **proof-of-concept study** to support future funding applications

What you need to commit

Time

- **2-3** total days to August
- Then **1 day/week** to April 2023

Enthusiasm for working with peers on an international outcomes study

The backing of **your employer** and supporting resource if needed (e.g., data scientists)

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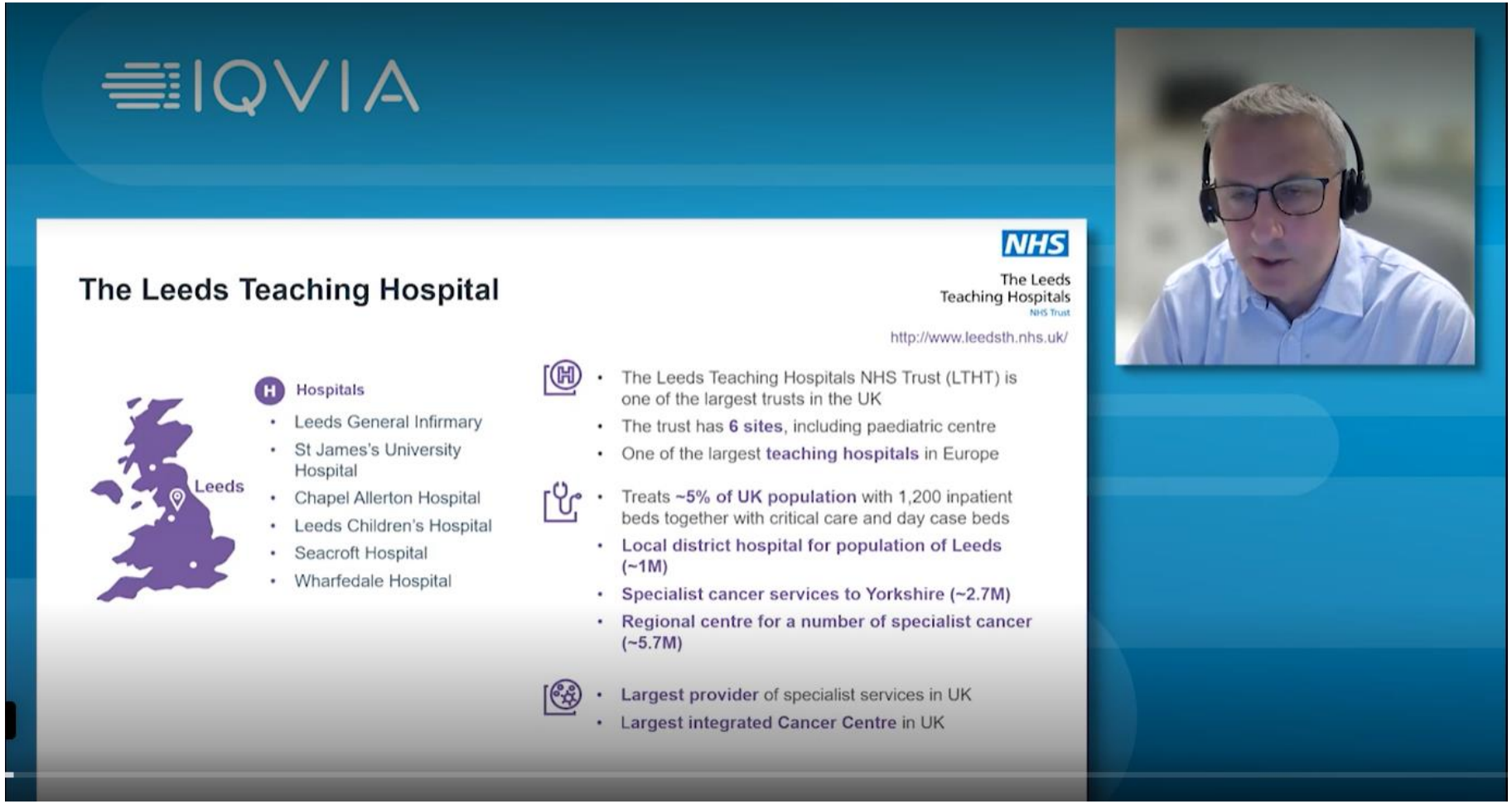
Case study: ORWIC



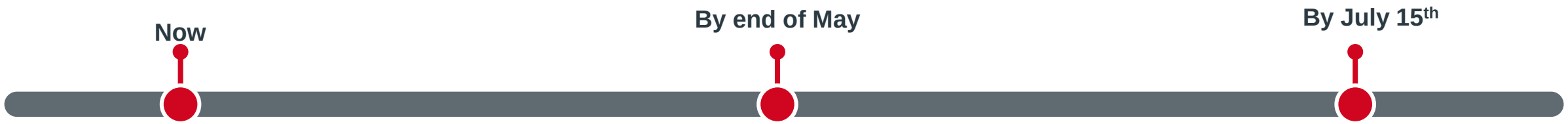
ORWIC Q&A

I'm interested! What do I need to do?

Enrol on the course
- https://tinyurl.com/IDEAL4RWEenrol
- Confirm eligibility: <45, Europe-based, not-for-profit

Form a study leadership team
- 3+ sites in 3+ countries
- Tumour focus

Develop a study protocol
- Submit application (as a team)
- Seek your employer's support



- We will support you to form teams
  - IDEAL4RWE seminar in May (date tbc) will include networking
  - We will create email distribution lists by tumour type
  - We can connect you to researchers in the DIGICORE network
- You can also reach out through your own network/outreach to authors

- We will support you to write the application
  - 2 IDEAL4RWE seminars in June (date tbc) will focus on application
  - We will provide an application template
  - We will provide a sample completed template

Registrants will also get access to three further training seminars, and FAQs on a SharePoint platform

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Study team – leadership team (July) and implementation team (Protocol submission)

You will need to start by identifying your leadership team

By July – leadership team

Role

- The "organising minds" for the international outcomes study
- Responsible for protocol, planning, resourcing, overall delivery, dissemination
- The future lead authors for the work
- Generally – but not exclusively – clinician researchers

Composition

- At least **3 sites/institutions** from at least **3 countries** – all in Europe
- Max 1 person per site/institution
- **1 patient representative**
- Up to 1 additional team member (e.g., other science discipline)
- **<45** will be given priority
- Commitment to **1 day/week/team member***

By October – delivery team

Role

- The delivery team for the study – all activities required for study delivery
- A range of different functions

Composition

- As for leadership team and also…
- At least two additional sites (may be outside Europe)
- Additional functional expertise as required (e.g., epi, data science, stats, clinical coders, additional clinicians) – no age restriction

*Preferably each team member can commit 1 day a week – where not possible, ½ day week with additional ½ day support (e.g., from research scientist) will be considered

We will be looking for individuals and teams who demonstrate enthusiasm, commitment and a vision for outcomes research

July submission and application assessment criteria

Content of submission

- Short bios of all team members and relevant and complementary experience (2-3 pages)
- TA and study objectives (1-2 pages)
- Cohort size by institution (1/2 page)
- Identified target data items and local formats (1 page table)
- Site-level legal basis for and approach to processing (1/2 – 1 page)
- Short term project plan (1 page)
- Evidence of institutional support (Letter of support)

Criteria for assessment

Assessment of initial study proposals will include evaluation of:

1. **Host centres of team members –** the suitability of the centres represented as collaborator in a proof of concept network
2. **Team skill mix –** the ability for the named collaborators to deliver the study
3. **Project proposal –** quality of the initial proposal outline
4. **Project delivery –** feasibility of the initial proposal within timescale

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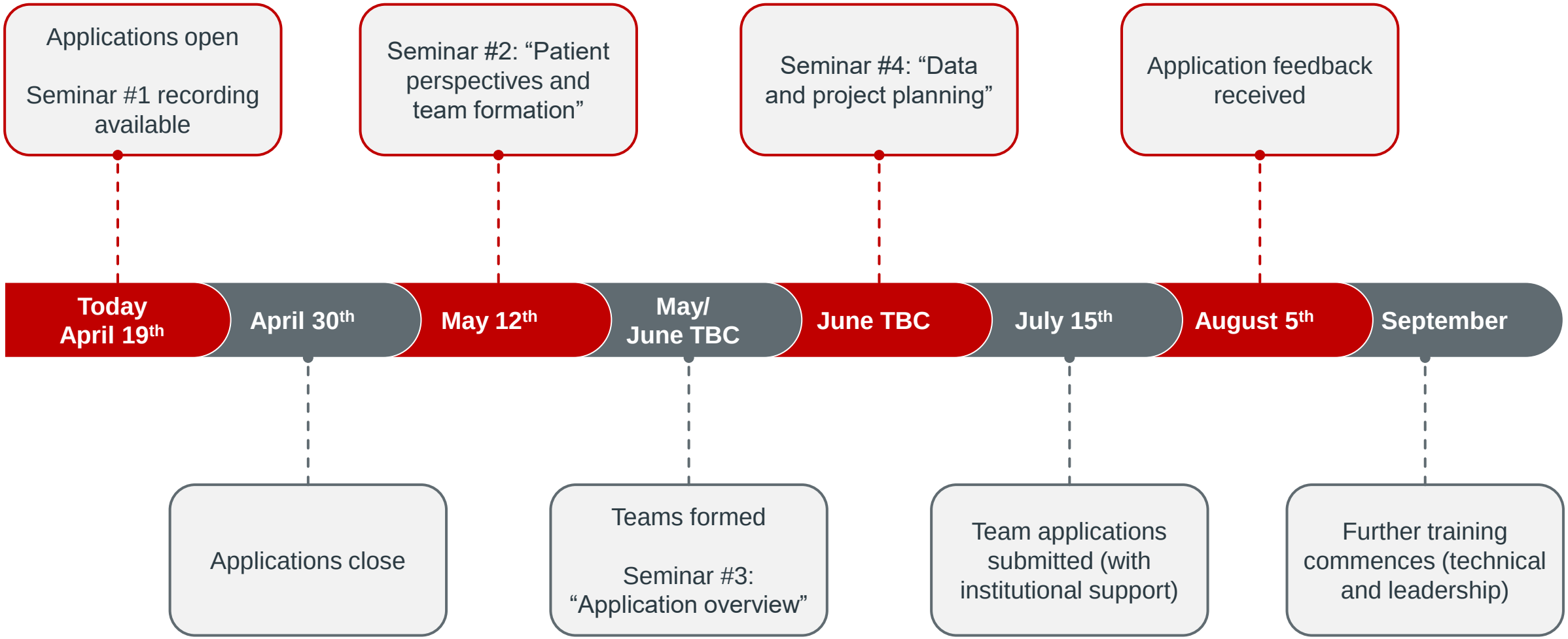
Questions?

You can also send questions to training@digicore-cancer.eu

What happens next?



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Thank you