Dynamic Consent

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OXF

ne engaged patient is
‘the blockbuster drug of the century

sh, HL7 Standards, 2012]

‘The Patient will see you now’ E. Topol, 2015

The move to patient empowerment: with digital tech at their fingertips, and access to all their data to drive their own decision-making and have greater choice in their care

Digital health – clinic and research

- Traditional separation between clinical care and biomedical research:

  ‘you will not receive any results’

  ‘research will not personally benefit you’

- Greater crossover as data increasingly flows back and forth between research and the clinic

ow do patients keep track of their data: what is bei
llected, stored, used and shared; and by whom?

Informed consent: definition

- 'Informed consent is a fundamental principle that has marked the emergence of modern medical ethics based on personal autonomy'
- It specifies the details of the proposed research and attendant risks and potential benefits
- Prerequisite of research involving human beings since the Nuremberg Trials

Report of the International Bioethics Committee of UNESCO (IBC) ON CONSENT, 2008

Informed consent: issues

Research shows:

- Consent forms long and complex
- A particular challenge to engage people from culturally and linguistically diverse backgrounds, lower literacy, different ages
- Lack of participant understanding, misconceptions about purpose of research, knowledge not retained
- Not a real choice – just a hurdle requirement

Informed consent for future use

Donating for unknown future use

Samples might be shared across organisations, national boundaries

Secondary findings

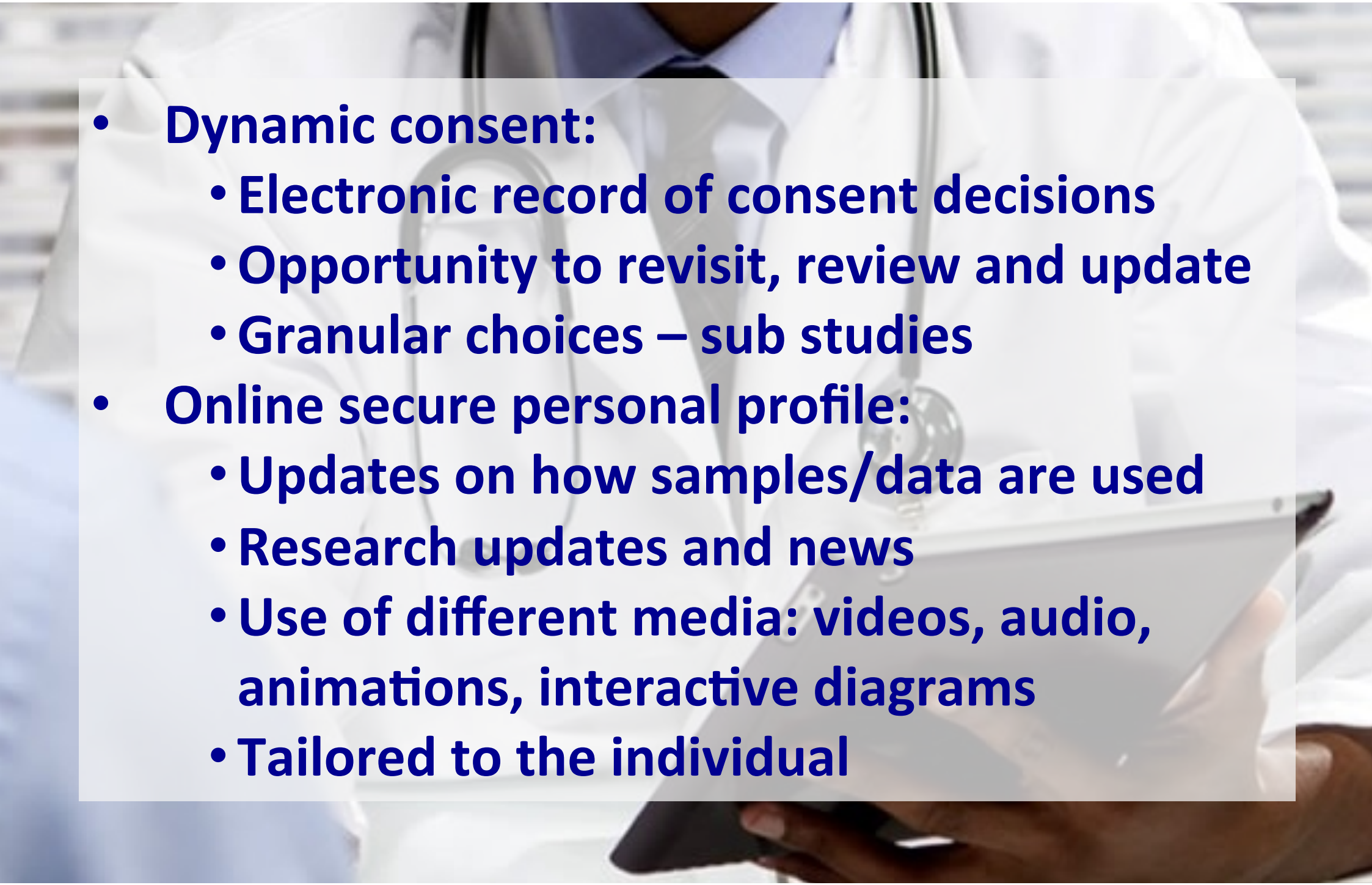
Recontact

Relevance to family members

Question of sustainability, changing legal landscape

Broad consent for future use

- Broad consent approach is common: covers as many future uses as possible.
- Accords with WMA Declaration of Taipei, and OECD Guidelines on Human Biobanks.
- BUT ethically and legally problematic: often research participants have no idea how their data and samples are being used



- Dynamic consent:
  - Electronic record of consent decisions
  - Opportunity to revisit, review and update
  - Granular choices – sub studies
- Online secure personal profile:
  - Updates on how samples/data are used
  - Research updates and news
  - Use of different media: videos, audio, animations, interactive diagrams
  - Tailored to the individual

What does Dynamic Consent do?

- Puts the participant at the centre of decision-makin
- Enables on-going communication with the research team
- Provides a secure record of all consents and interactions in one place
- Engages with individuals as part of a personalised medicine approach

e-consent vs DC

e-consent

- Electronic version of the same process
- Not clear if it counts as a ‘written signature’
- How do you verify identity?
- Replacing face to face?

Dynamic consent

- Requires a behaviour change – patients as partners
- Ongoing interaction
- Two-way communication
- Greater control
- May start with a paper form!

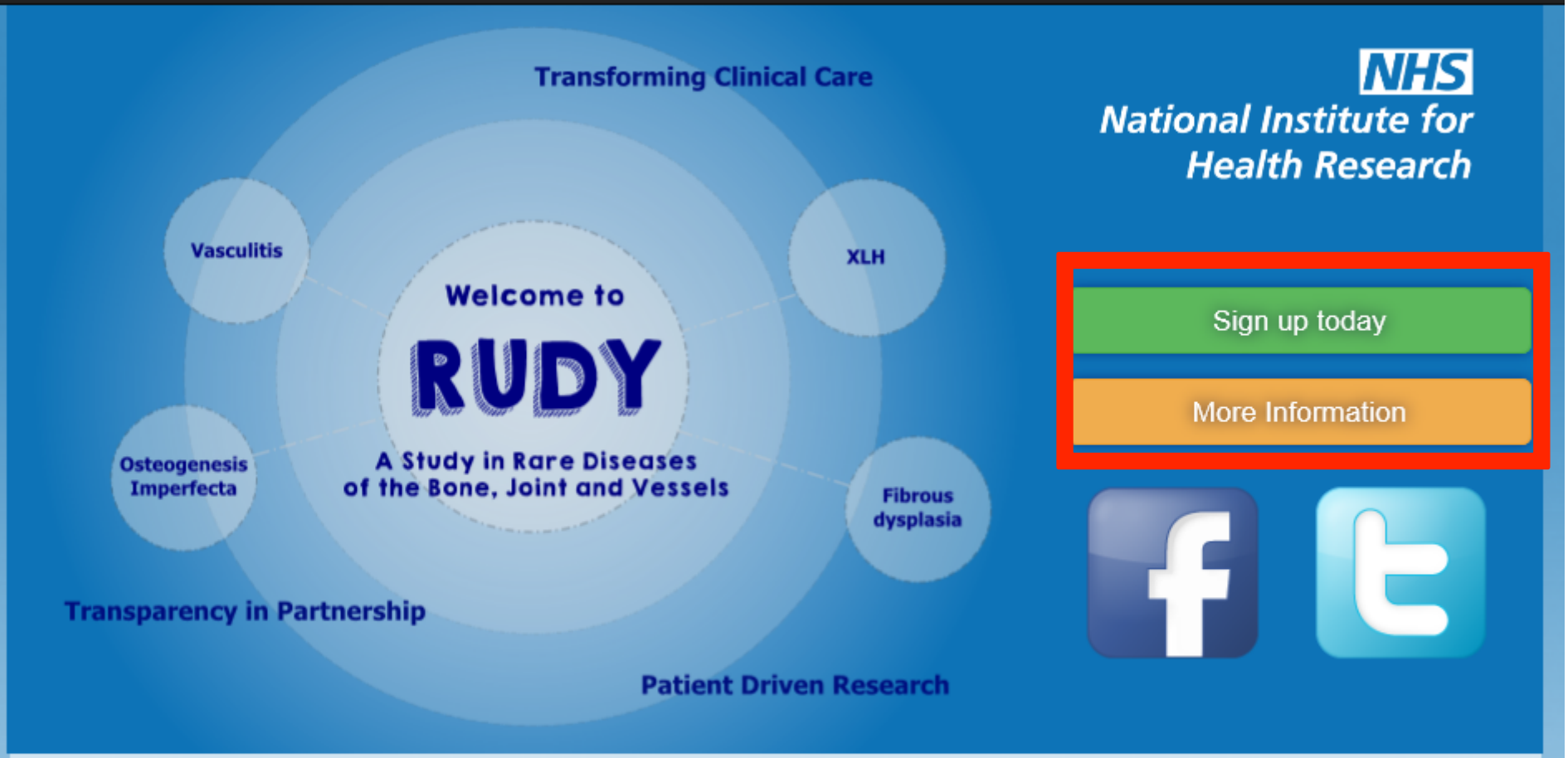
Common concerns:

- Will control over data hamper research?
- Can (and therefore will) people withdraw more easily?
- Will loss of control over data compromise the data-set?
- Is the cost / benefit worth it?
- What about people who don’t want to use computers?

Examples

RudyStudy.org

Researchers | Library | Log In



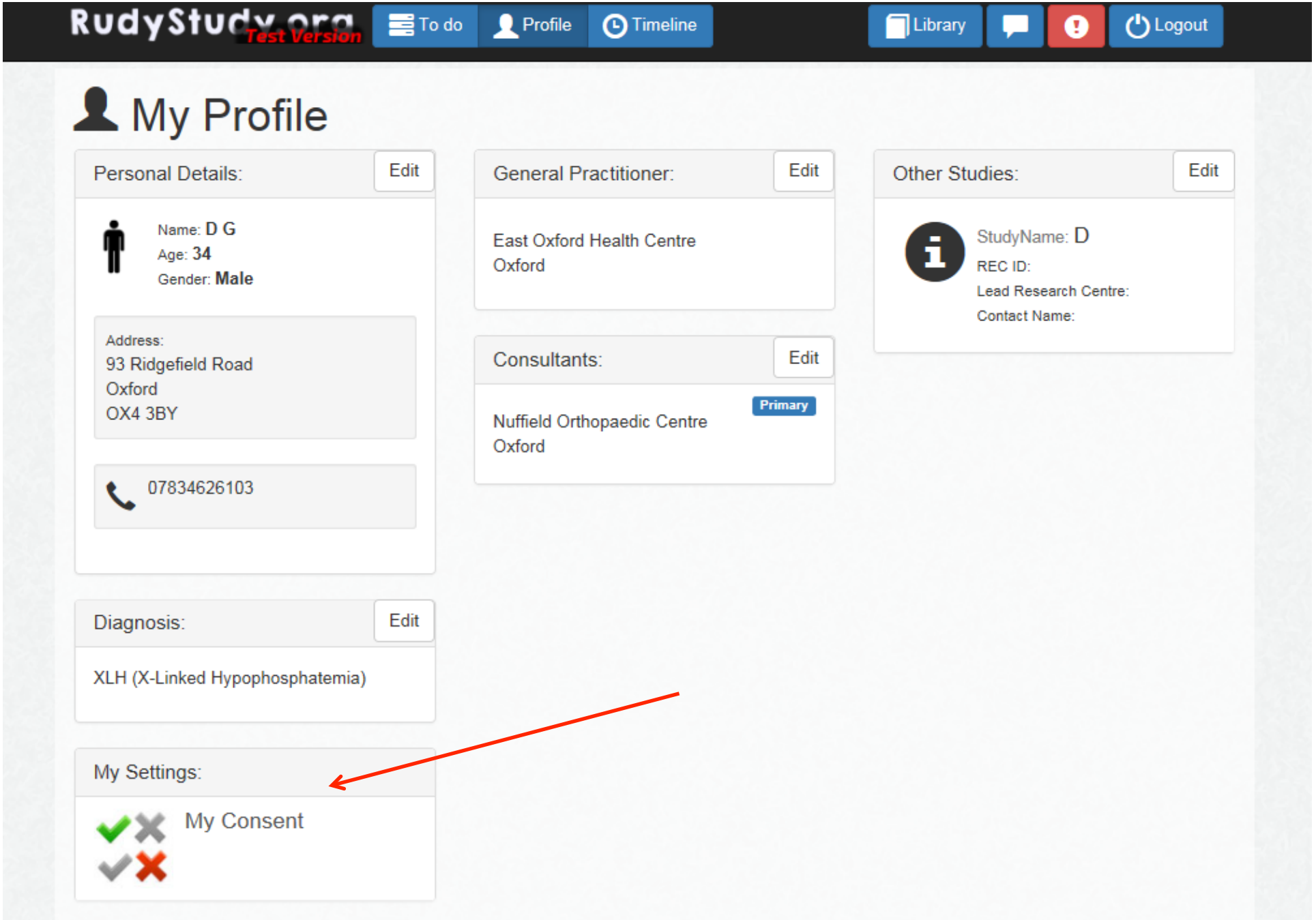
NHS
National Institute for
Health Research

Sign up today

More Information

What is Rudy?

Rudy is a study in Rare diseases of the bones, joints and blood vessels. Headed up by a research team at the University of Oxford, Rudy aims to transform clinical care for participants through patient driven research.


RudyStudy.org
Test Version
To do
Profile
Timeline
Library
Logout
My Profile
Personal Details:
Edit
Name: D G
Age: 34
Gender: Male
Address:
93 Ridgefield Road
Oxford
OX4 3BY
07834626103
General Practitioner:
Edit
East Oxford Health Centre
Oxford
Consultants:
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Primary
Nuffield Orthopaedic Centre
Oxford
Other Studies:
Edit
StudyName: D
REC ID:
Lead Research Centre:
Contact Name:
Diagnosis:
Edit
XLH (X-Linked Hypophosphatemia)
My Settings:
My Consent

My Consent

Events

I agree to provide information about *previous* events and consequences using my secure personal profile on the RUDY website and for this information to be made available to the RUDY research team

I agree to provide information about current and future events and consequences using my secure personal profile on the RUDY website and for this information to be made available to the RUDY research team

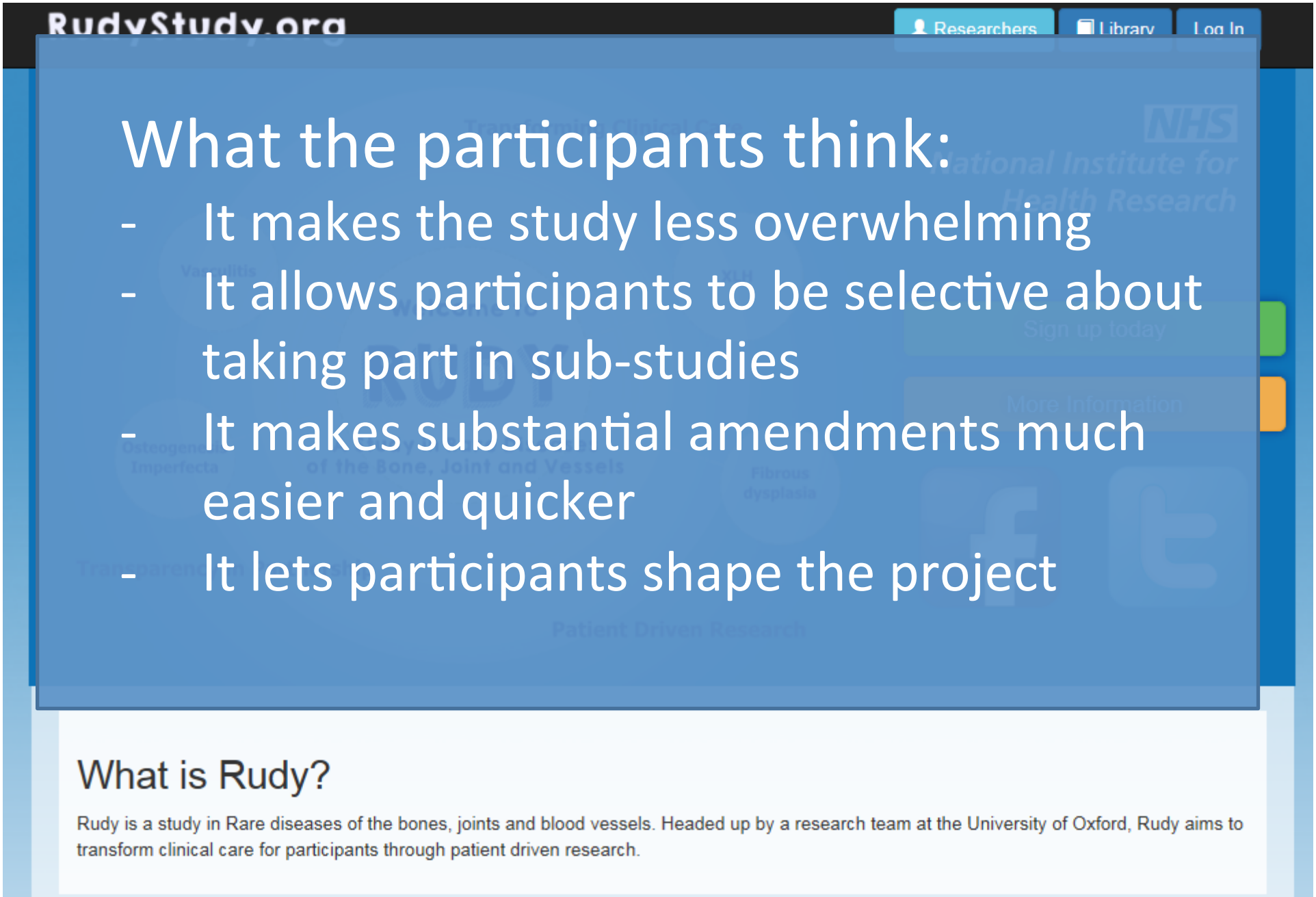
Records

I agree that my previous NHS and social care medical records can be made available to researchers.

I agree that my current and future NHS and social care records can be made available to researchers.

Samples

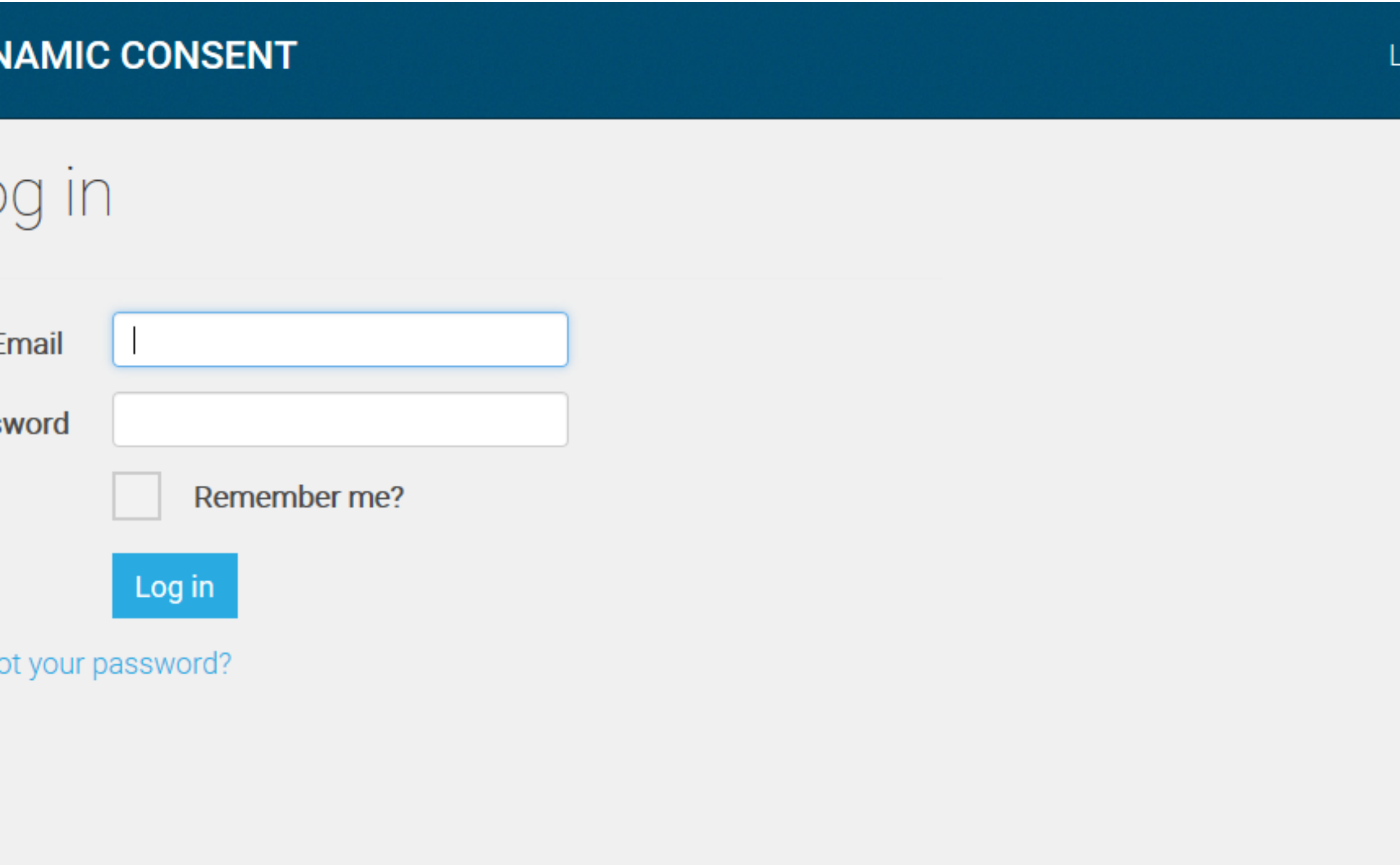
I agree that any tissue removed in the course of medical care related to my condition may be used by the researchers. I consider this tissue a gift and I understand I will not gain any direct personal or commercial benefit from this.


RudyStudy.org
Researchers
Library
Log In
What the participants think:
- It makes the study less overwhelming
- It allows participants to be selective about taking part in sub-studies
- It makes substantial amendments much easier and quicker
- It lets participants shape the project
What is Rudy?
Rudy is a study in Rare diseases of the bones, joints and blood vessels. Headed up by a research team at the University of Oxford, Rudy aims to transform clinical care for participants through patient driven research.

NAMIC CONSENT

Log

The GCOF Simulation Project is developed in the context of the 'Genetics Clinic of the Future'. It enables members of the consortium to go beyond a theoretical consideration of the challenges ahead, by gaining firsthand experience of having their genome sequenced. The 'Genetics Clinic of the Future' (GCOF) starte on January 1 2015 as a 2.5-year research project, granted by the H2020 Framework of the European Commission (HCO15-643349-GCOF).


NAMIC CONSENT
L
og in
Email
sword
Remember me?
Log in
ot your password?

GCOF 004

I agree to take part in video documentation of the GCOF simulation process.

GCOF 005

I agree to take part in video documentation of the GCOF simulation process.

GCOF 006

I agree to take part in video documentation of the GCOF simulation process.

GCOF 007

What the participants think:

- Concept is good in principle but needs a complete eco-system to support it
- It is the direction of travel – 'the only way…to make meaningful sense of what informed consent and giving consent means'
- Disagreed on how consent should be organised – some wanted to consider everything, others wanted a 'yes to all'

Platform for Engaging Everyone Responsibly (PEER)

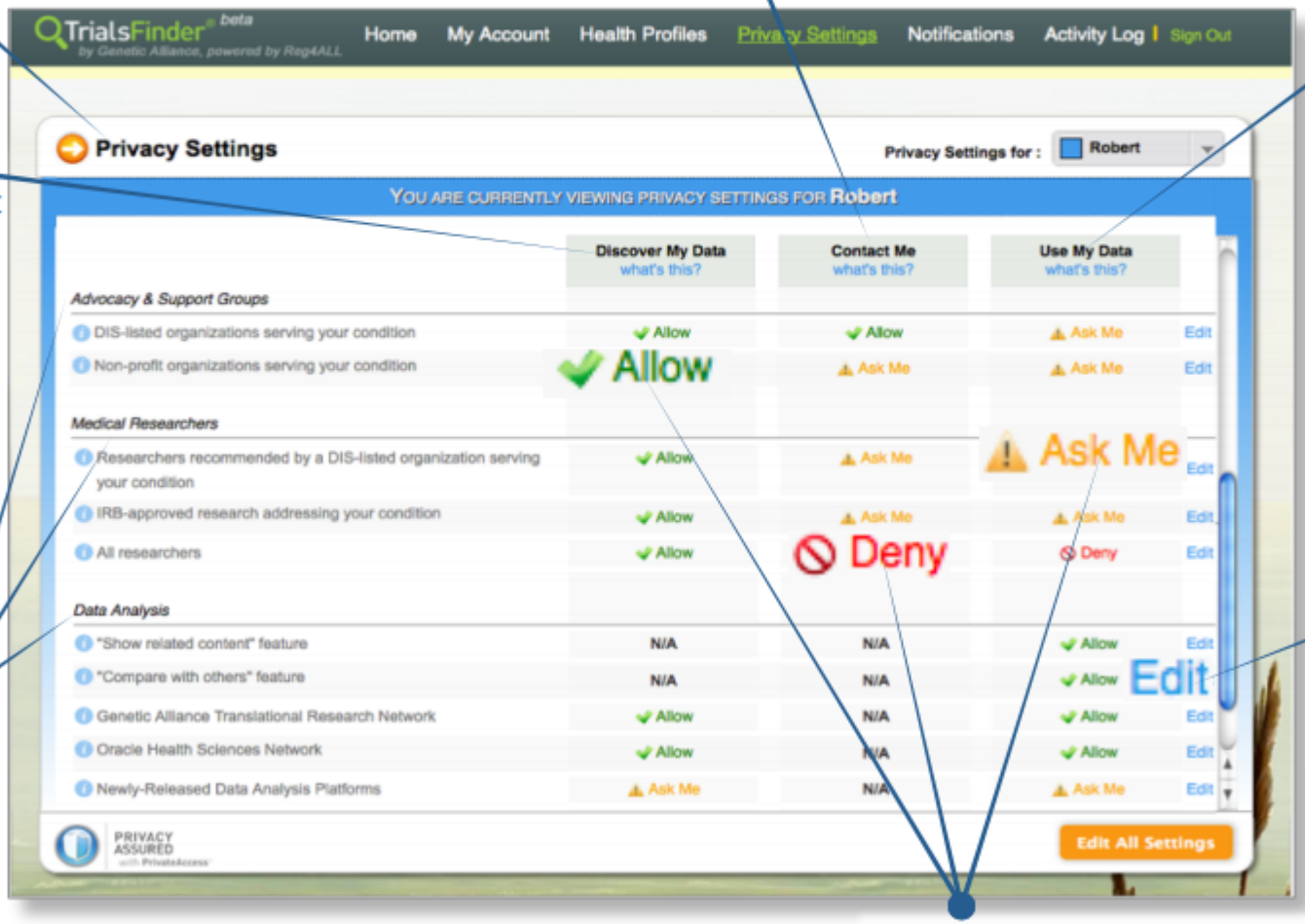
PEER enables a range of granular access controls, with ease

Participants use access controls to specify who can, and cannot, access or use their data, and for what purpose

"Contact Information" And separately, who can have access to their contact information

"Use" And who can use or export data from the PEER system

"Discovery" Each participant controls who can locate their de-identified data…



For multiple categories of uses, and specified usage rights

This can include:
Bridge
Personal Genome Project
PatientsLikeMe, and so on

And given the option to Permit, Decline, or wait for more information before deciding

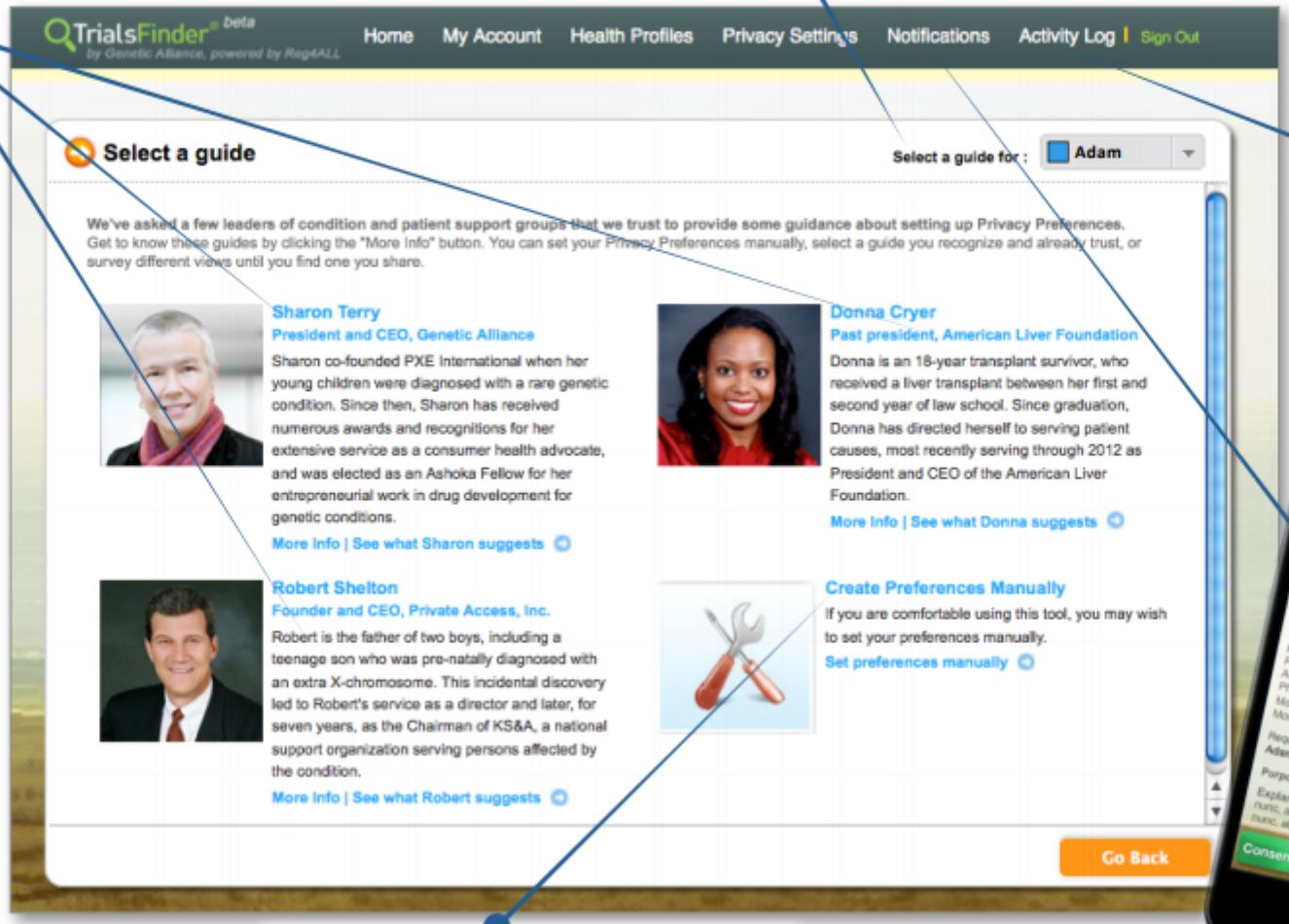
And the opportunity to change these preferences over time[1]

[1] *So long as the data is in PEER or a system that adheres to the person's Private Access settings.*

With a highly intuitive guide structure, notifications & dynamic consent

Participants can draw support from knowledgeable members of their community about considerations regarding data sharing and access controls

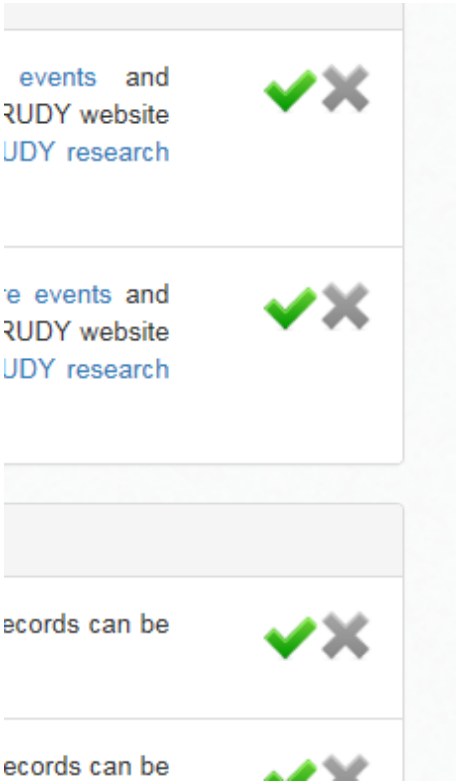
…and do this for each member of their family, or use an existing group of settings as the basis for others

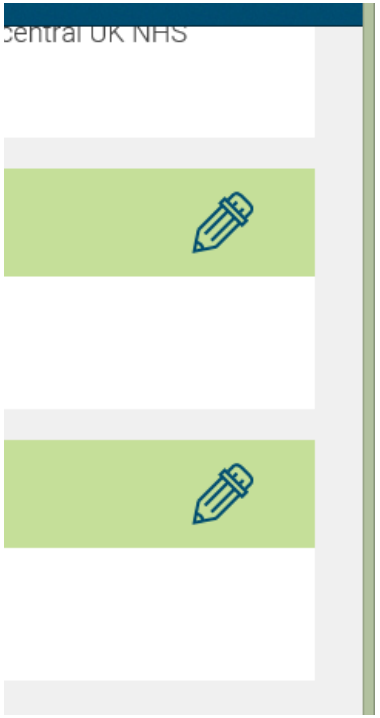


And with an easily accessible audit log for all activity being maintained at all times

With dynamic consent from a computer or a smartphone

…or set their preferences manually, without influence by anyone





Granular choices
Tailoring involvement
Change mind over time
Ongoing interaction

- Engagement, not just consent

Dutch projects:

The Personal Health Train (PHT) (and the MyConsent tool) aims to increas
the interoperability and (re-)use of health data. The two main concepts
behind the PHT are that (i) data stay with, and are controlled by the data
owner or custodian and (ii) research (questions and analyses) are brought t
the data and executed using distributed learning technologies (Peter-Bram
Hoen – Radboud UMC).

kDus (*It's Me*) – an online personal health environment which allows an
individual person to manage his/her health data. This data can be gathered
from different sources, such as a hospital, a diagnostic laboratory, a biobar
and also directly from the individual (Marleen Schippers – UMC Groningen)

Does it work?

namic Consent: An Evaluation and Reporting Framework

rnal of Empirical Research on Human Research Ethics

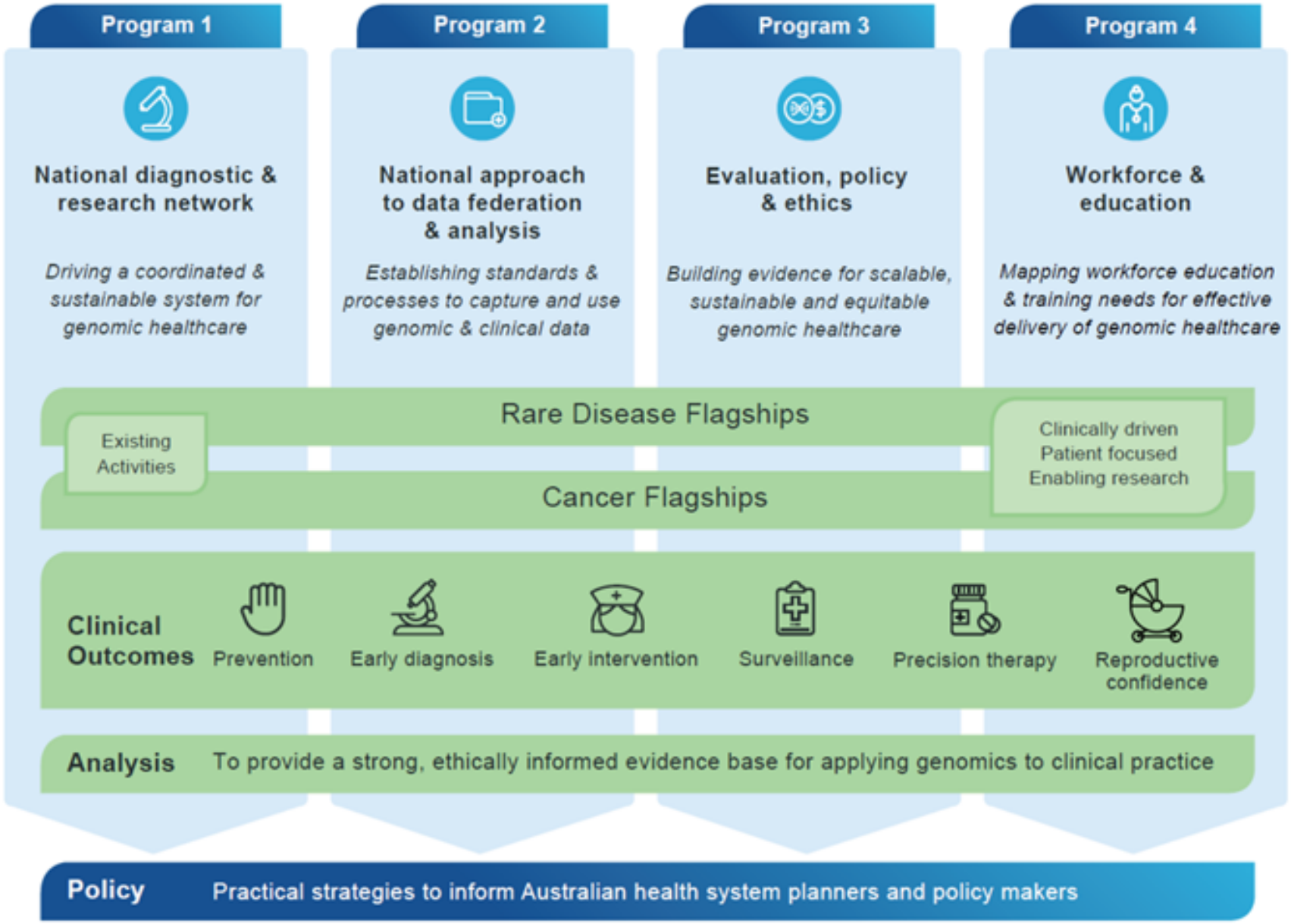
v 2019

gan Prictor[1], Megan A. Lewis[2], Ainsley J. Newson[3], Matilda Haas[4, 5], Sachiko Baba[6], Han
a[7], Minori Kokado[6], Jusaku Minari[8], Fruzsina Molnár-Gábor[9], Beverley Yamamoto[10], Jan
e[1, 11,] Harriet J. A. Teare[1, 11]

Australian Genomics: DC Evaluation

Australian Genomics is preparing Australia for the integration of genomic medicine into healthcare. We are providing the evidenc needed to transform the diagnostic process, inform the healthca workforce, and to show how genomics is best delivered in the clinical setting.

Australian Genomics Health Alliance


Program 1
National diagnostic & research network
Driving a coordinated & sustainable system for genomic healthcare
Program 2
National approach to data federation & analysis
Establishing standards & processes to capture and use genomic & clinical data
Program 3
Evaluation, policy & ethics
Building evidence for scalable, sustainable and equitable genomic healthcare
Program 4
Workforce & education
Mapping workforce education & training needs for effective delivery of genomic healthcare
Rare Disease Flagships
Cancer Flagships
Existing Activities
Clinically driven
Patient focused
Enabling research
Clinical Outcomes
Prevention
Early diagnosis
Early intervention
Surveillance
Precision therapy
Reproductive confidence
Analysis
To provide a strong, ethically informed evidence base for applying genomics to clinical practice
Policy
Practical strategies to inform Australian health system planners and policy makers

DC pilot – launched in Dec 2018

- Piloting new online platform ‘CTRL’
- Allows participants to choose more specific consent options and receive information about the research
- 2 participating flagships:
  - chILDRANZ (child interstitial lung disease)
  - HIDDEN (end-stage kidney disease)
- Randomised participation – DC vs paper consent
- Baseline survey and 6 month follow up

Australian Genomics
Health Alliance

Welcome to CTRL

Consent for participating in the Australian Genomics program

Register Now

Log in

Challenges for the evaluation:

- Trying to coordinate a study within a study
- Adding survey questions to existing surveys – without making them too onerous
- Fitting with flagship timelines (including ethics amendments)
- Building in option for patients to decline using DC
- Engagement focus as part of next phase

Thank you!

- HeLEX Centre, Oxford
- HeLEX@Melbourne
- GCOF partners – Terry Vrijenhoek, Bogi Eliasen, Daan Schuurbiers
- Dynamic consent partners (Including RUDY and the AGHA working group)

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