

Dynamic consent – using IT in health research



Dr Harriet Teare
University of Oxford

HeLEX

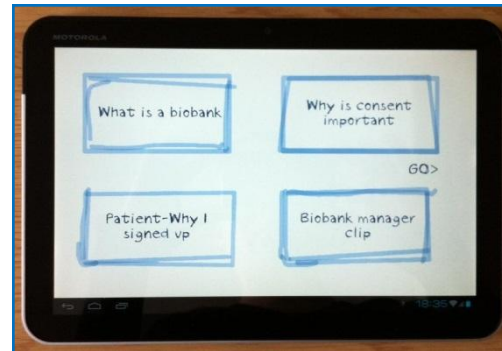
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Use of IT in research

- Providing information
- Conducting research
- Hearing from participants
- Research governance





**ECMC annual network meeting
21st May 2015**

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- ‘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*

- 'broad' or 'blanket' consent for biobank research raises ethical and legal questions – it provides authorisation or permission, for a broad range of research purposes that were not specified at the time of recruitment
- Informed consent **cannot be** applied to biobanking if the proposed research is not known at the time of consent
- *Caulfield, T.; Kaye, J. Med. Law Int. 2009, 10: 85*

2. Can we make more of consent?

I Agree

I Disagree

Consent:

...is a legal requirement

...gives participants control

...is entry to the study

...is the start of a conversation

...‘covers’ the researcher

...sets up a partnership

3. The Dynamic Consent Model

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- **Electronic consent: with consent preferences stored online, to revisit, consider and update.**
- ***Sticky policies***
- **Online secure personal profile – with updates on how your samples/data have been used**
- **Research updates and biobank news**
- **Use of different media: videos, audio, animations, interactive diagrams**
- **Tailored to the individual – what do you want to know, and when?**

4. Dynamic consent in practice

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Transforming Clinical Care



*National Institute for
Health Research*

Welcome to
RUDY

A Study in Rare Diseases
of the Bone, Joint and Vessels

Vasculitis

XLH

Osteogenesis
Imperfecta

Fibrous
dysplasia

Transparency in Partnership

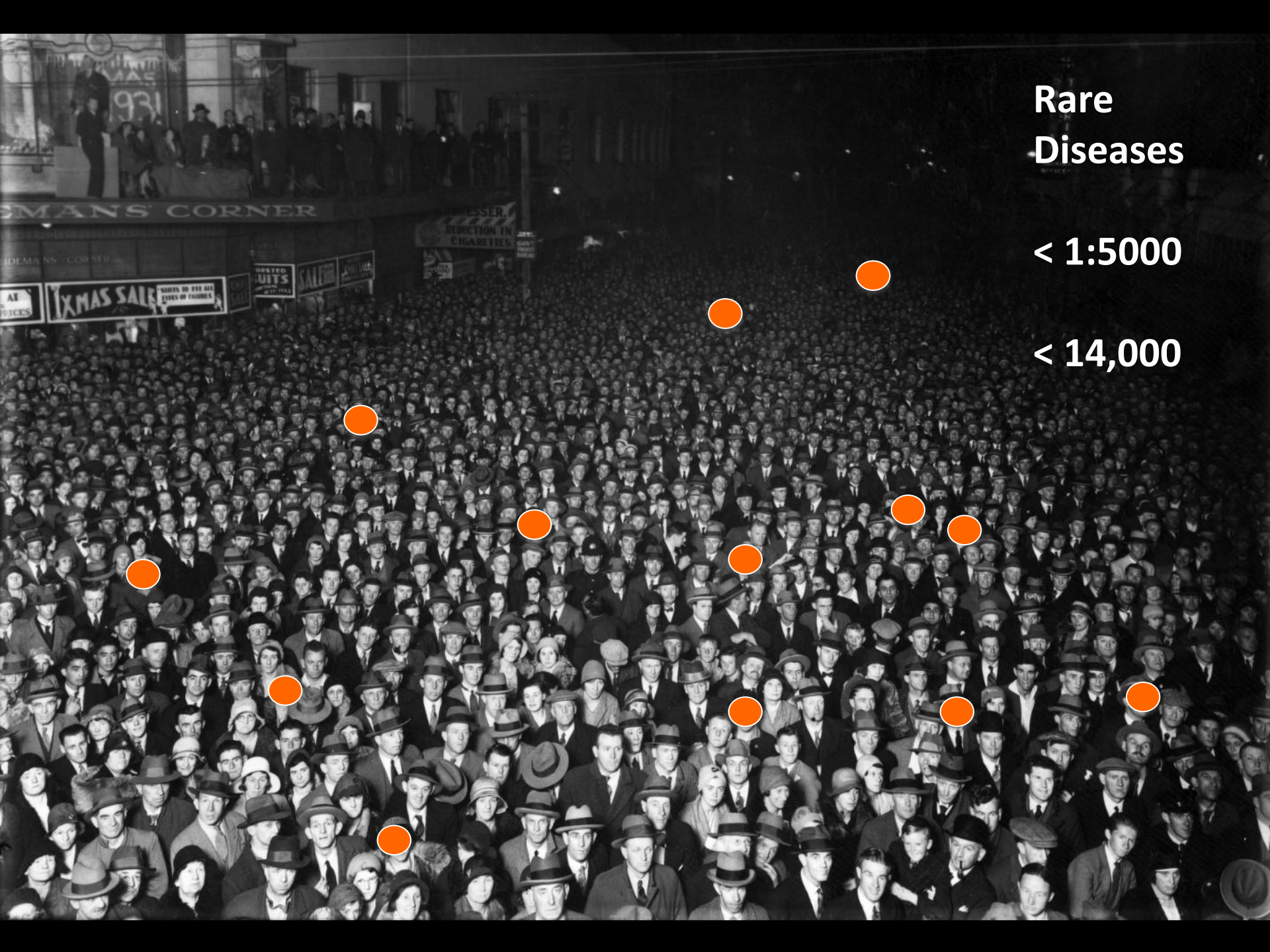
Patient Driven Research

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.



Rare Diseases

< 1:5000

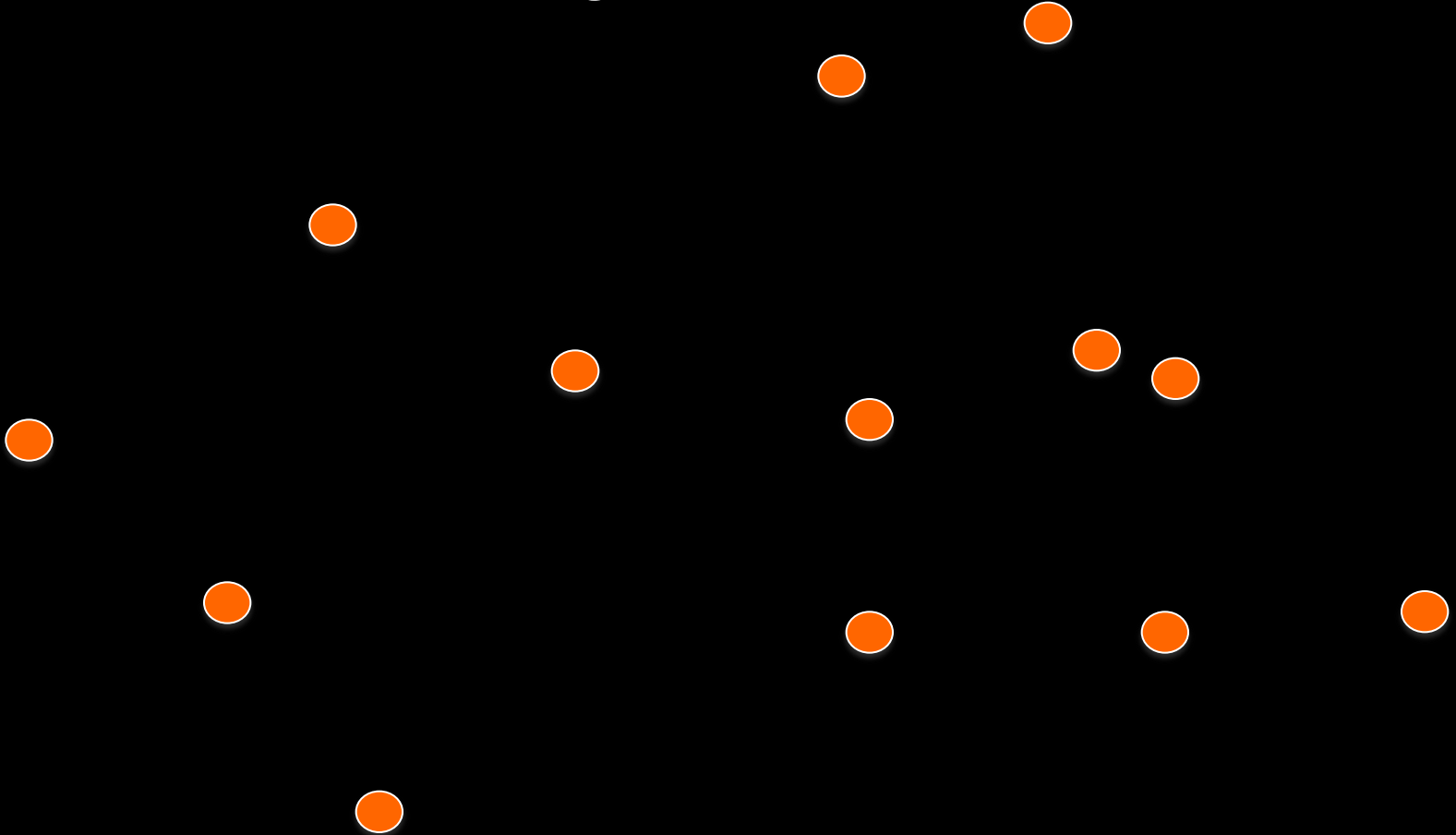
< 14,000



Rare diseases are Under researched

Information for patients and doctors is fragmented

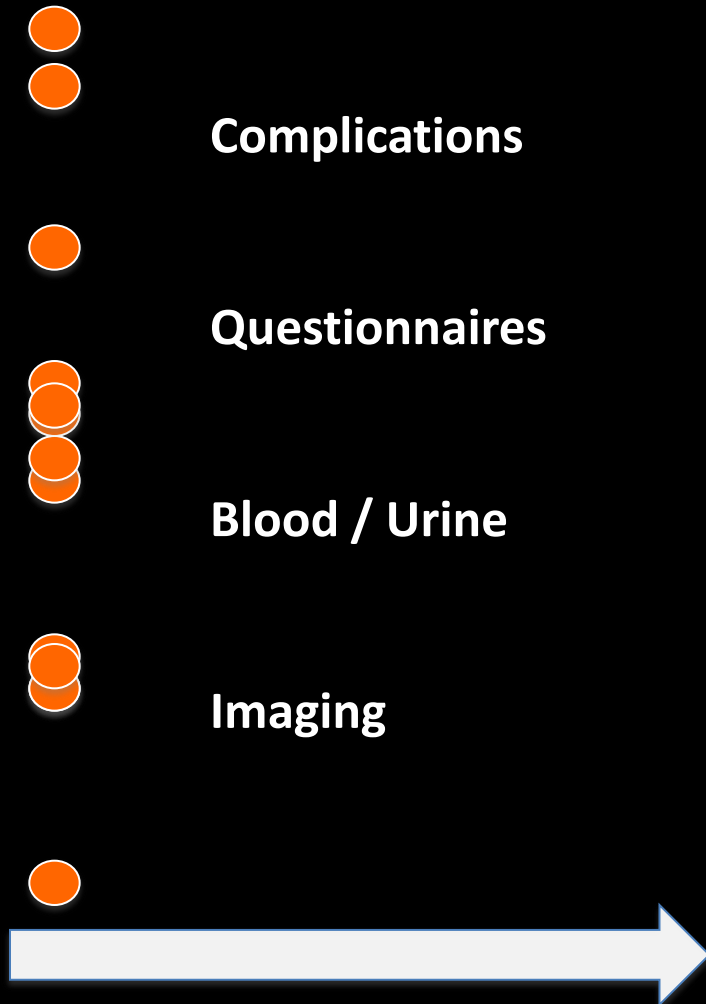
Limited evidence for informing care



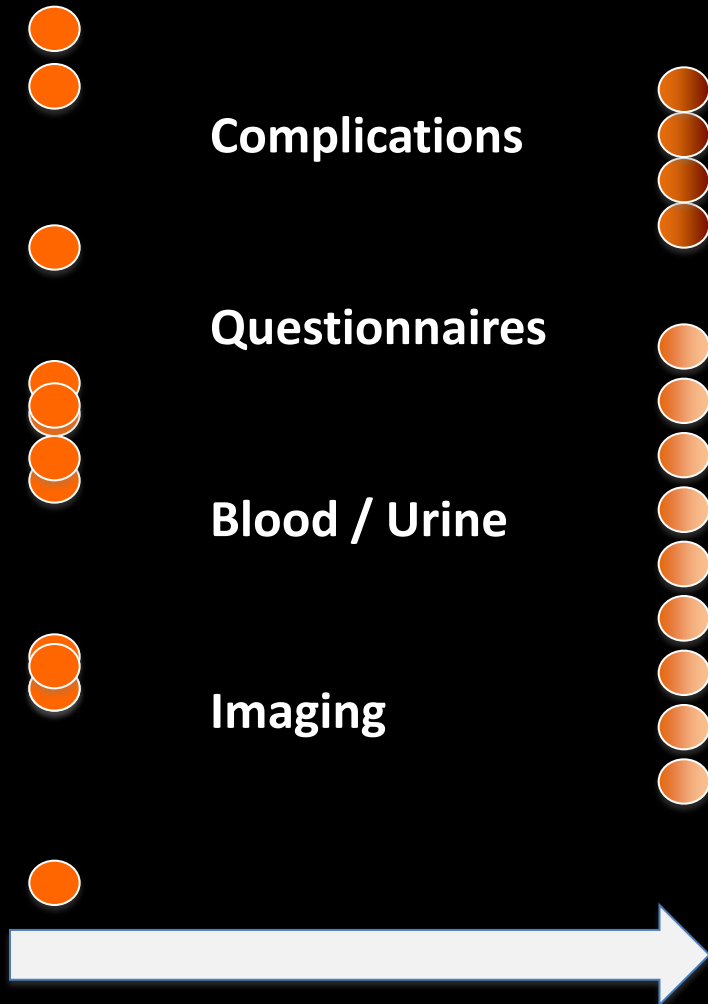
Identify and recruit



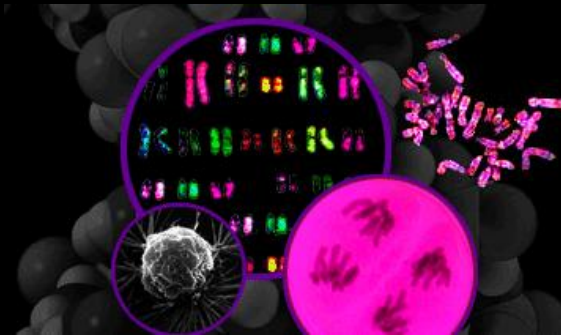
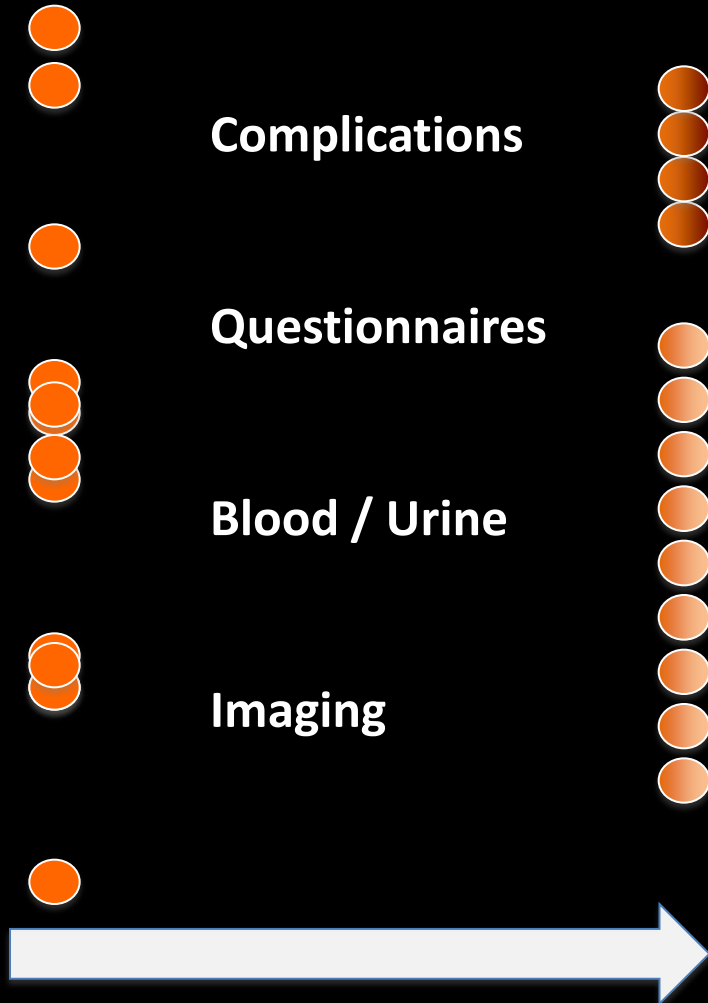
Systematic assessment



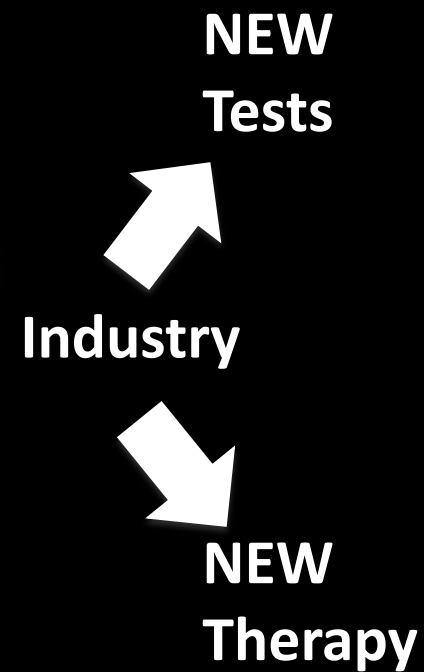
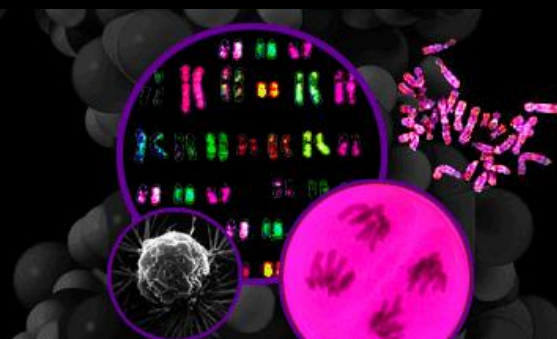
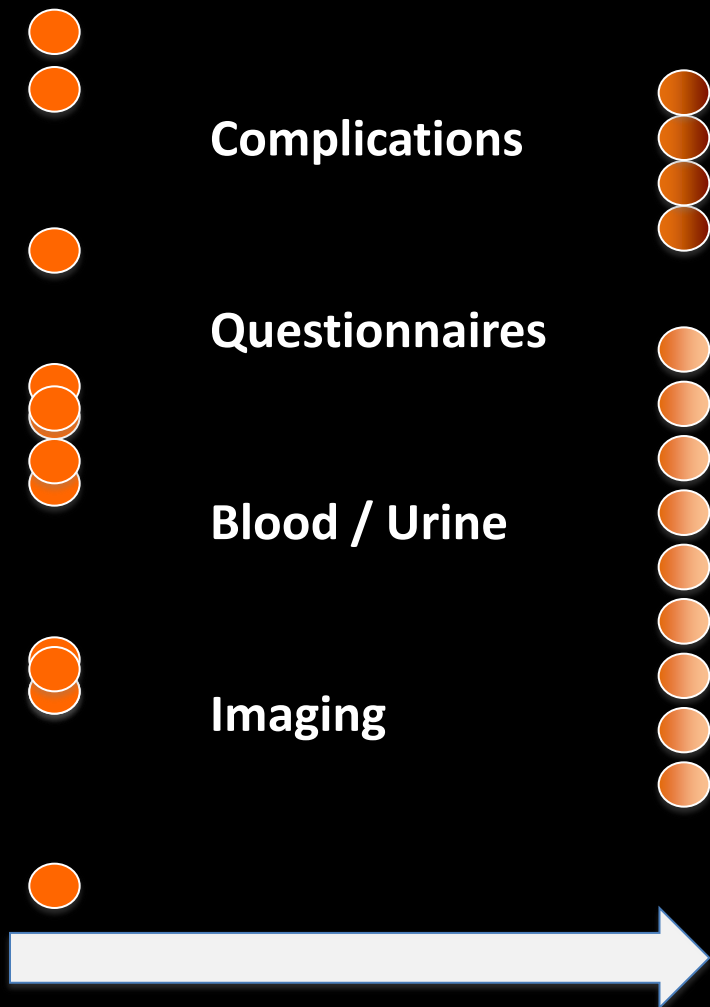
Identify novel subgroups



Explore biology



Transform clinical care



Transforming Clinical Care



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Health Research

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⌚ Thank you for your interest in the study. This registration process should take only a few minutes of your time.

ⓘ It is important that all sections of this registration are completed if you are considered for the study. If, for any reason, you are unable to complete the registration, you will be removed from the study. Please contact your doctor or re-register if you are unable to complete the registration.

Sign Up

I have read the [Participant Information Sheet](#).

Are you the participant?

I am the participant

I am registering on behalf of the participant

- Arrange a telephone call to consent
- Consent form signed and returned
- Diagnosis confirmed with doctor
- Participants provided with login

Postcode

Postcode

How did you find out about RUDY?

Doctor, Nurse or GP

Did you receive an invitation letter? Please tick here.

Email address

@

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:

Edit

Nuffield Orthopaedic Centre
Oxford

Primary

Other Studies:

Edit



StudyName: D
REC ID:
Lead Research Centre:
Contact Name:

Diagnosis:

Edit

XLH (X-Linked Hypophosphatemia)

My Settings:



My Consent

To do

Whats New



Timeline & Fracture map now online!

We have recently updated Rudy with new features. You can now add your fracture history to your timeline. To get started click [here](#).

Questionnaires

Every 6 months you will be invited to fill out a selection of questionnaires. These help us to track your health through time, and may offer valuable insights to researchers seeking to understand your condition.

Pain 2

PainDetect

Submitted

Quality of Life 2

SF36 Health Survey

Not yet started

Rheumatic Illness

PedsQL

Not yet started

Childhood Health

CHAQ

Not yet started

Pain

Wong / Baker Faces

Not yet started

FACIT

Fatigue scale for chronic illness

Not yet started

Pain 1

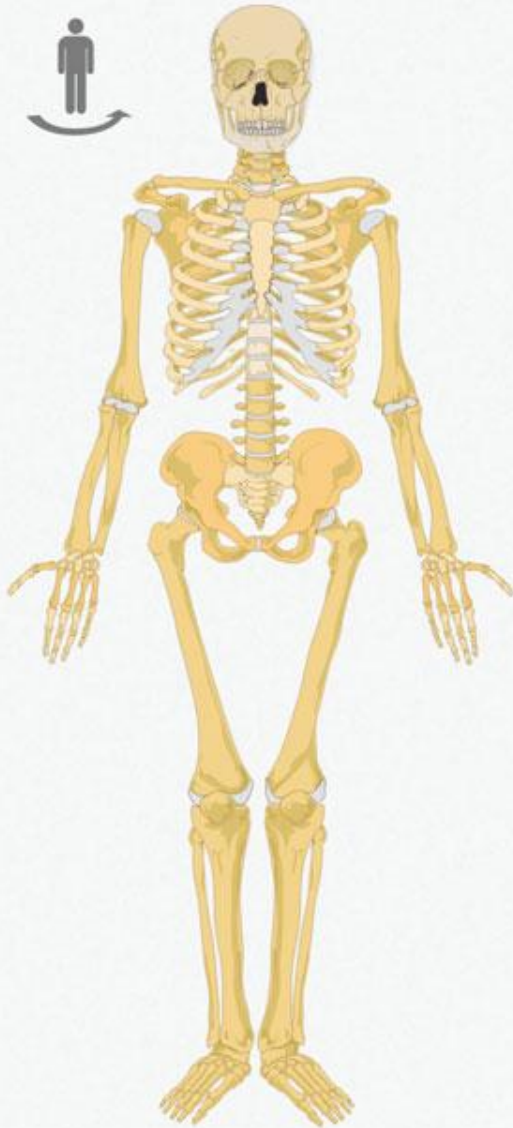
Sleep

Quality

Recent Activity

- saved fracture: Childhood 1 week ago
- Appointment selected. 2 weeks ago
- Changed consent options. 2 weeks ago
- submitted paindetect questionnaire 1 month ago
- saved paindetect questionnaire 1 month ago
- saved fracture: 1 month ago
- saved psqi questionnaire 3 months ago
- saved eq5d questionnaire 3 months ago
- submitted adl questionnaire 3 months ago
- saved adl questionnaire 3 months ago

Fracture Event:



Fracture Details

Date of Fracture

Level of Trauma

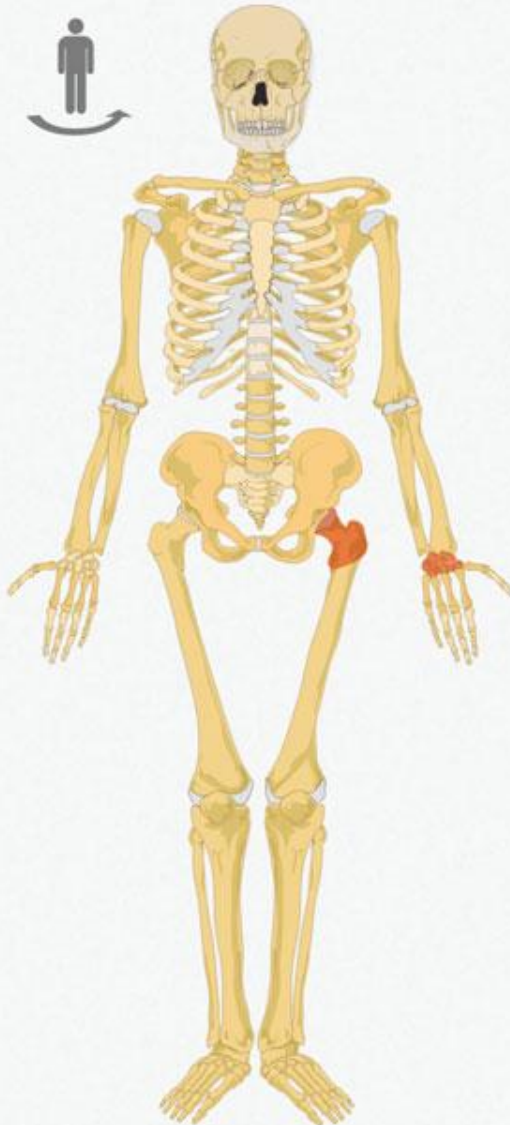
Trauma Level 1: e.g. Spontaneous

Fractured Bones

Cancel

Next

Fracture Event:



Fracture Details

Date of Fracture: 14/02/2008

Level of Trauma

Trauma Level 3! e.g. intermediate

Fractured Bones

Search

Left Hip
Fracture Count: 1 2 3 More than 3

Left Wrist (Carpals)
Fracture Count: 1 2 3 More than 3

Cancel Next

My Timeline

+ Add a fracture

2015

2012

Fracture:
06/05/2012

Right Upper Arm
Left Upper Arm
Right Upper Leg
Left Upper Leg
Sternum
Skull
Vertebrae C1 (Cervical)

 Prednisolone (Prednisolone) 2.5mg gastro-resistant tablets

Dosage: **half**
Date started: **20/03/2015**
Date finished: **27/03/2015**

1989

Fracture:
My childhood
05/04/1989 - June 2004

Skull

 Prednisolone (Prednisolone) soluble tablets

 Alendronate (Alendronic acid)

1981

Fracture:



Library

Study Documents

Participants

Researchers

Study Documents

Participant Information sheet

The participant information sheet details what participation in the RUDY study will involve for you as a participant. Please select the relevant version for your age category. We require that every participant reads the Participant information sheet **before** signing up for the study, and for participants under 18 their parent/legal guardian must read the Parent/Guardian information sheet.



Participant Information sheet for Adults

This version is designed for all readers aged 16+



Participant Information sheet for Parents / Legal Guardians

This version is intended for all parents and legal guardians.



Participant Information sheet for Children aged 11-15

This version is designed for all readers aged 11-15 years.



Participant Information sheet for Children aged 6-10

This version is designed for all children aged 6-10 years.



Participant Information sheet for Children under 6 Years

This version is designed for all readers aged 5 years or less.

Consent Forms

It is up to you to decide whether to join the RUDY study. The Participant Information Sheet will

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:

Edit

Nuffield Orthopaedic Centre
Oxford

Primary

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.



✓ My Consent

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Records

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



Samples

I agree that a sample of my blood can be used as a gift and I understand that I will not benefit from the results.

Genetic research

Genetic research is the study of genes that are present in our cells and are the 'instructions' which control our how our body works. When one or more parts of the gene(s) change then the differences may be enough to causes symptoms that make up a rare disease. By looking at which genes are altered we hope to improve our understanding of why and how diseases occur, which will allow us to develop better tests and treatments.

I agree that my care related samples can be used for this tissue for commercial purposes.



I agree that my samples can be used for research and [commercial](#) purposes.

I agree that my samples can be used for personal or commercial purposes.

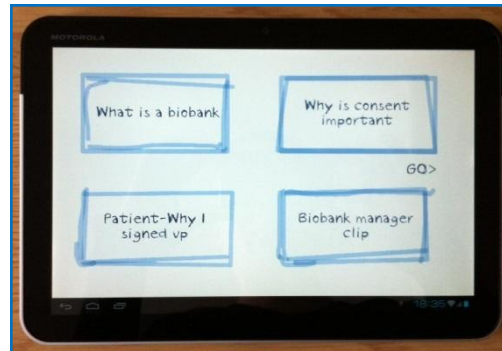


I agree that my donated samples can be used in [genetic research aimed at understanding genetic basis for rare diseases](#) and that any results that are [clinically important](#) as judged by the [Rudy Data Oversight Governance Committee](#) will be sent to the clinical team caring for me.



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Acknowledgements

- Making Connections and ELSI 2.0 collaborators
- EnCoRe Project members
- HeLEX Centre
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- Oxford Biobank
- OxPaRRM
- The DIRECT Project



harriet.teare@dph.ox.ac.uk

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