



Patient Centric Trials ICR Forum 6th September

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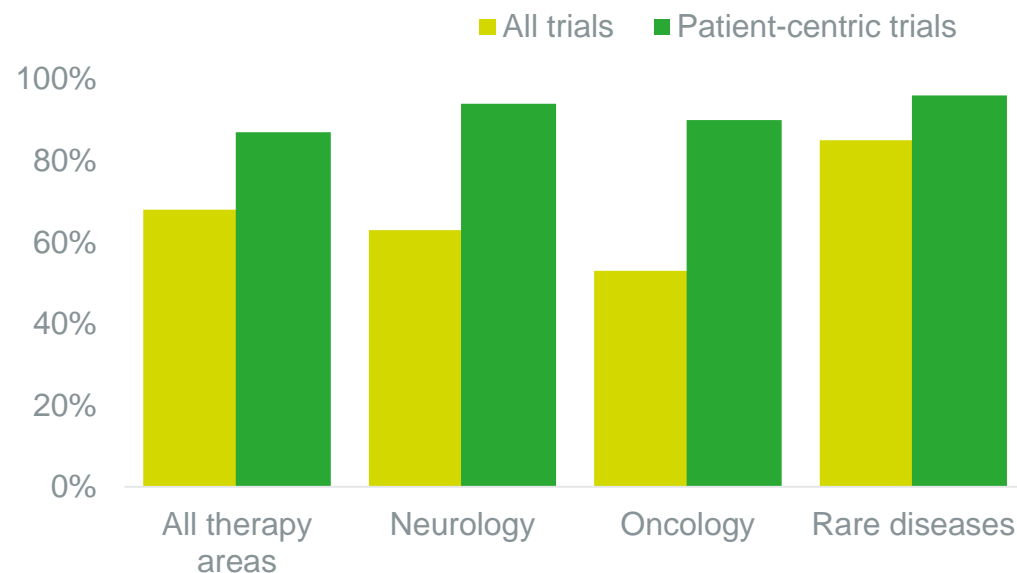
September 2019

Patient-Centric Design: Impact

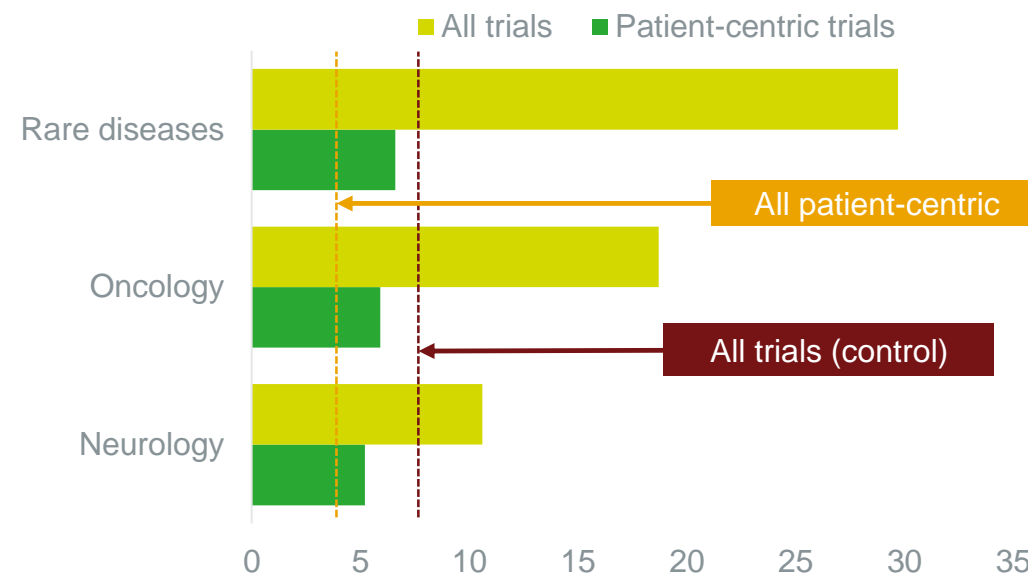
Investigational treatment **19%** more likely to launch

Approximately **40%** shorter recruitment period

Phase II and III likelihood of launch for patient-centric trials vs. all trials



Average time to enroll 100 participants for patient-centric trials vs. all trials (months)

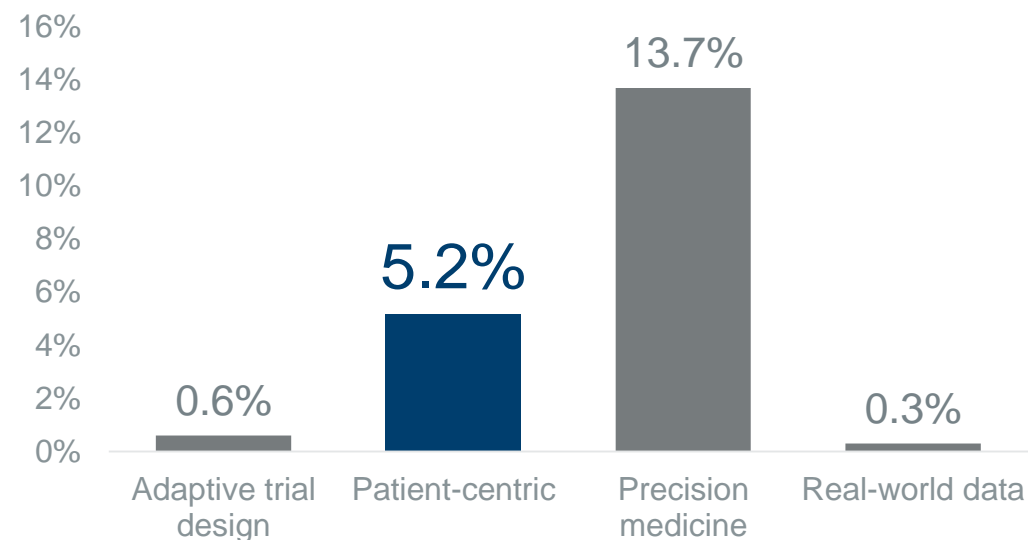


Patient-Centric Design: Impact

Only **1** out of 20 studies included a patient-centric design

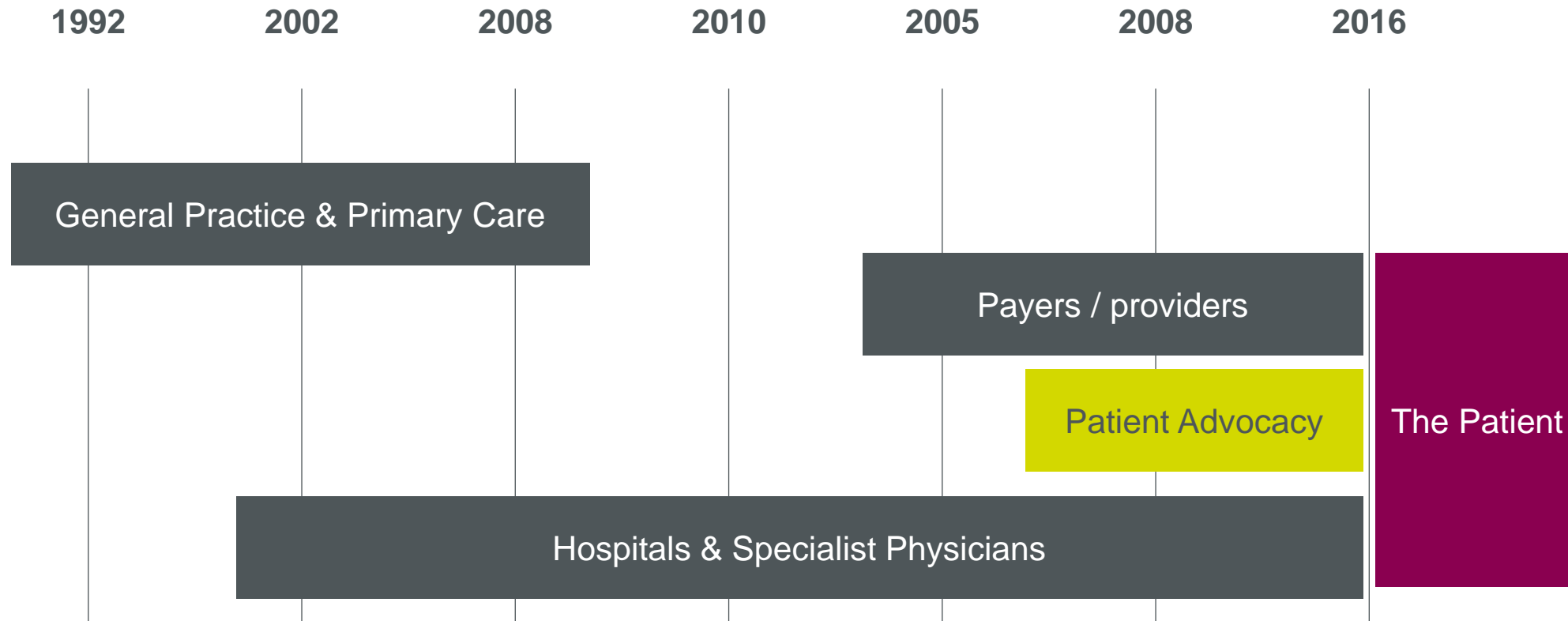


Adoption rates of selected innovations*



* Innovation adoption rate is defined as the number of Phase II & Phase III trials indicating use of innovation during the above period, as percentage of trials where innovations were not present from the same period of time.

Patient as a stakeholder – the evolution of personalised medicine





Patient-Centric Trials

Simplify the patient journey

- Design around **patient needs**
- Improve **relevance and convenience** to participate

Using language & images the patient relates to...

Websites, Digital Banners,



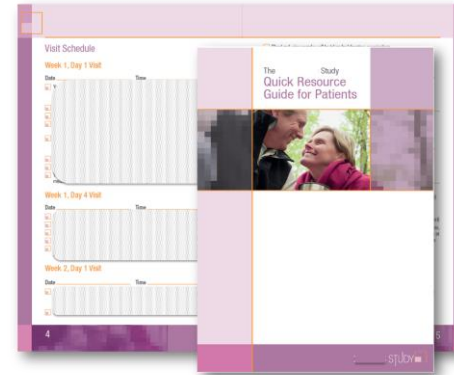
EDUCATE / ENGAGE

iPAD, ICF Flip Charts, Consent+ Aid tools



CONSENT / RANDOMISE

Visit by Visit Study Guides



PARTICIPATION / VISITS

Greater Gift - Thank You and Appreciation Cards



COMPLETION



APPs Study Posters and Flyers



APPs & Digital Study Brochures, Dear Patient Letters



Study Fact Sheets, Appointment Reminder cards, and Compliance Aid Tools



Patient & Study Alumni, End of Study Lay summaries

How many steps removed is the patient relative to each study?

PATIENT / DISEASE SUPPORT GROUPS

Local awareness & engagement campaigns

RADIOGRAPHY DEPT.

Assessing the links and relationships with all other members of the MDT, incl. CT, MRI, PET etc.

SURGICAL UNIT

Setting up patients effectively for i.e. Biopsy, lumpectomy etc.

GENERAL MEDICINE

Patients presenting with early symptoms, or flare etc.

ONCOLOGY OUTPATIENT CLINIC

Understanding patient motivation during the different stages of treatment

PHARMACY

Looking at proxy medications on repeat Rx as patient source

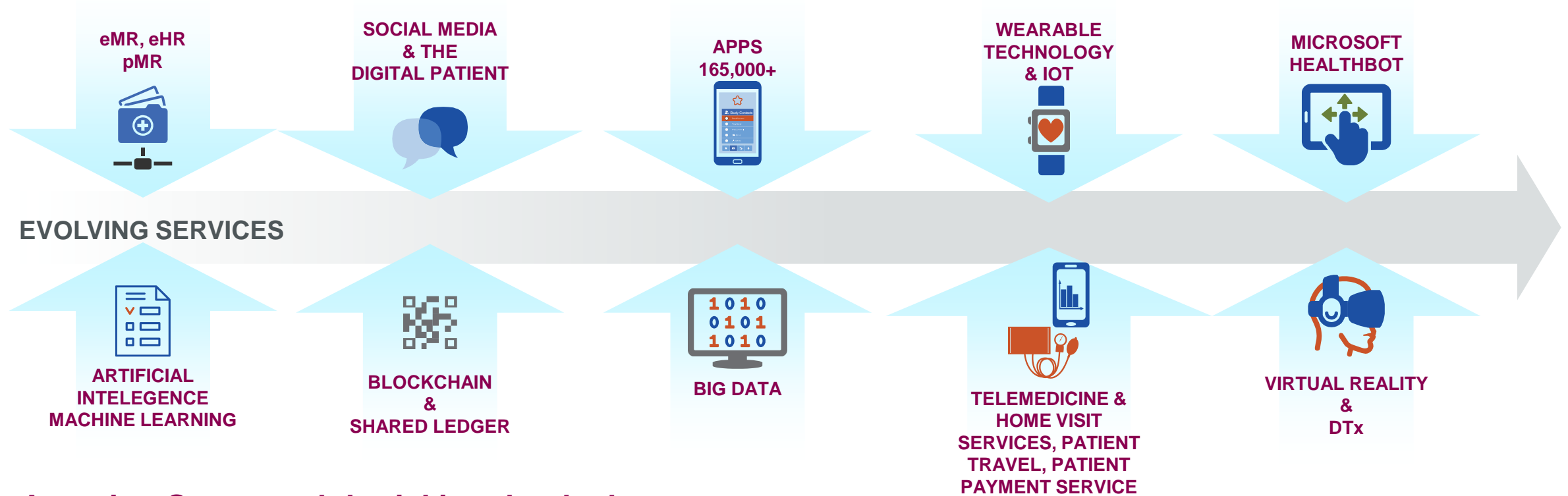
PRIMARY CARE

Mild or asymptomatic patients managed in primary care, several steps from site

Specialist Nurse Teams
Macmillan, Marie Curie, etc. Providing information on studies involving nurses & patients.



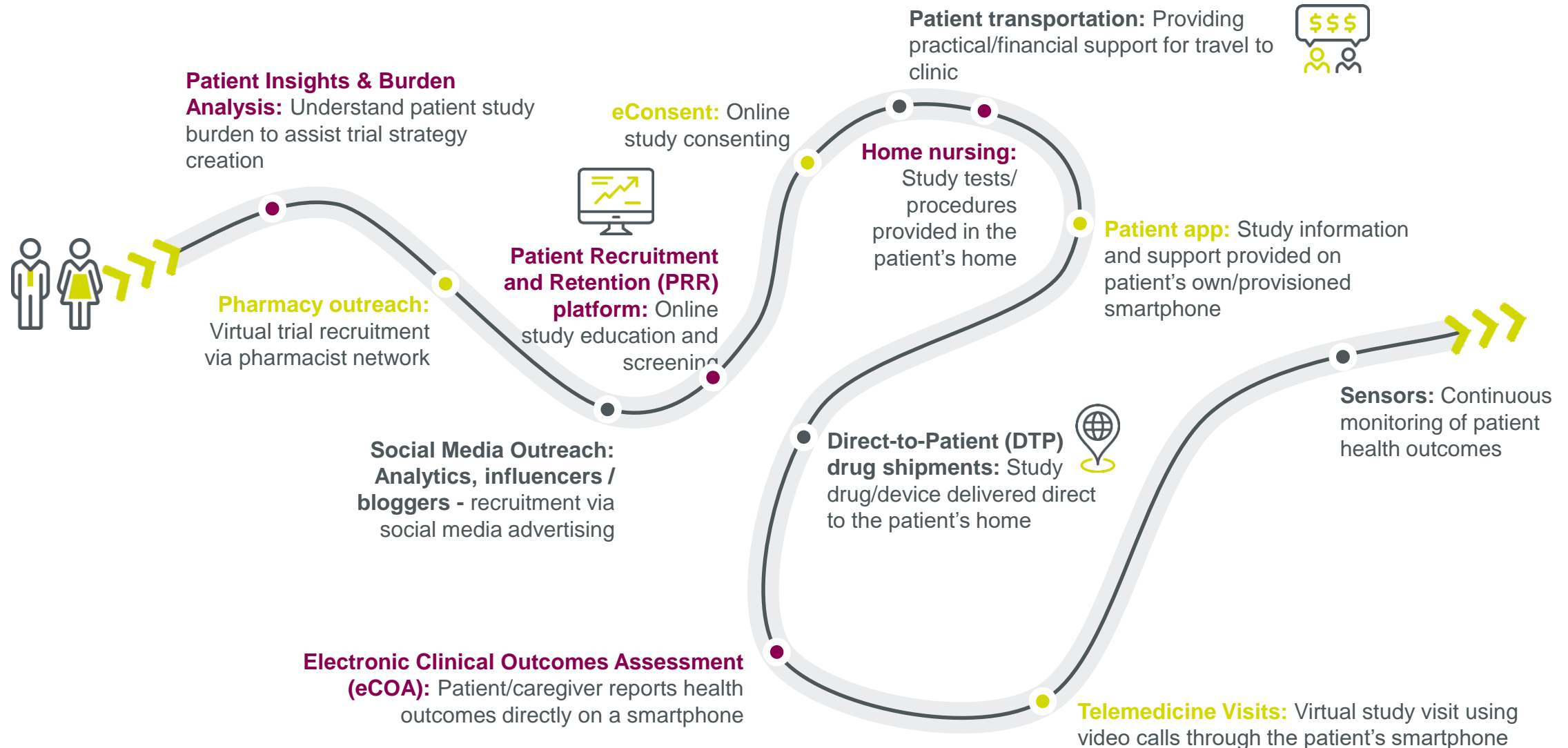
Dealing with innovation – at the inflection point



Agreeing Scope and de-risking the deployment:

- Eye always on the deliverable – randomised patients!
- Keep it simple for patients and sites
- Scope set jointly between using probability scoring for risk
- Negotiating risk based agreements with vendors on
- Risk assessment and de-risking inclusion of innovation tactic on a study

Mapping the patient pathway from insights – virtual studies



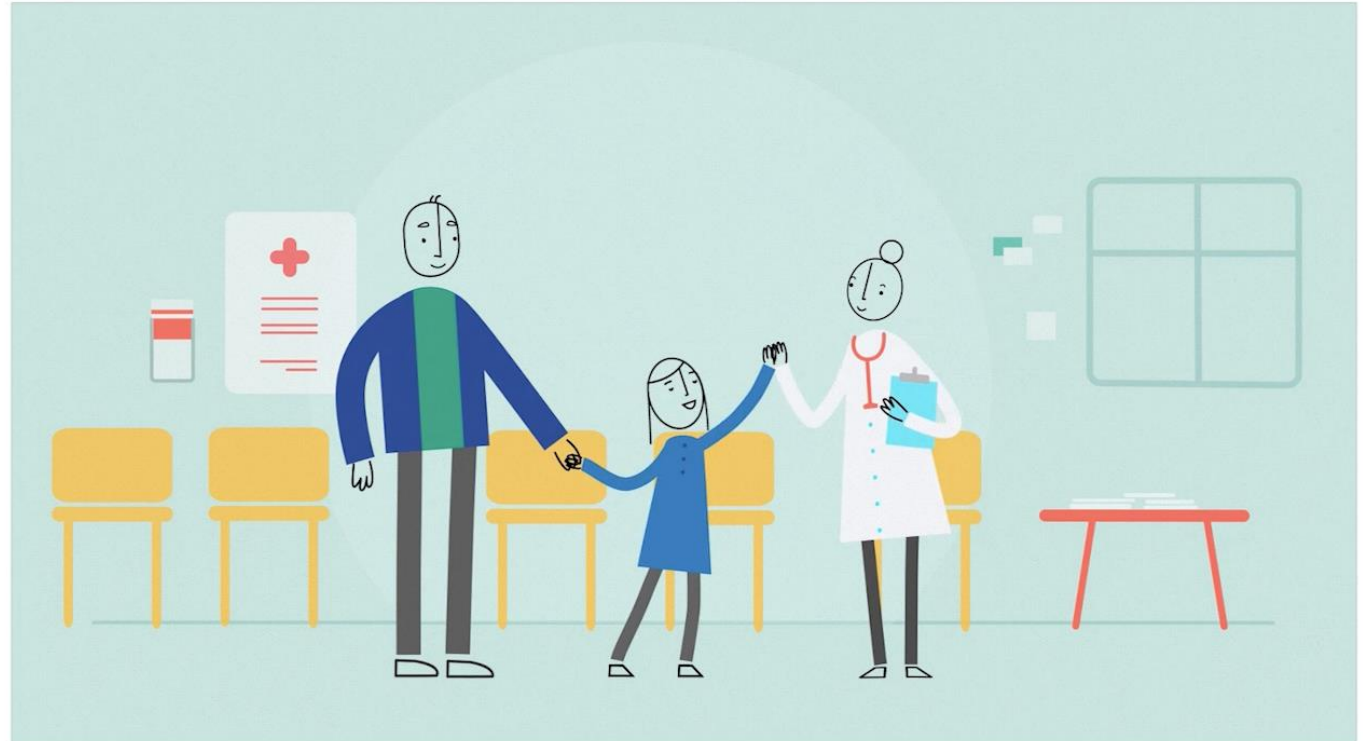
Informed consent

Decoding the clinical trial – the IBD / IBS lesson...



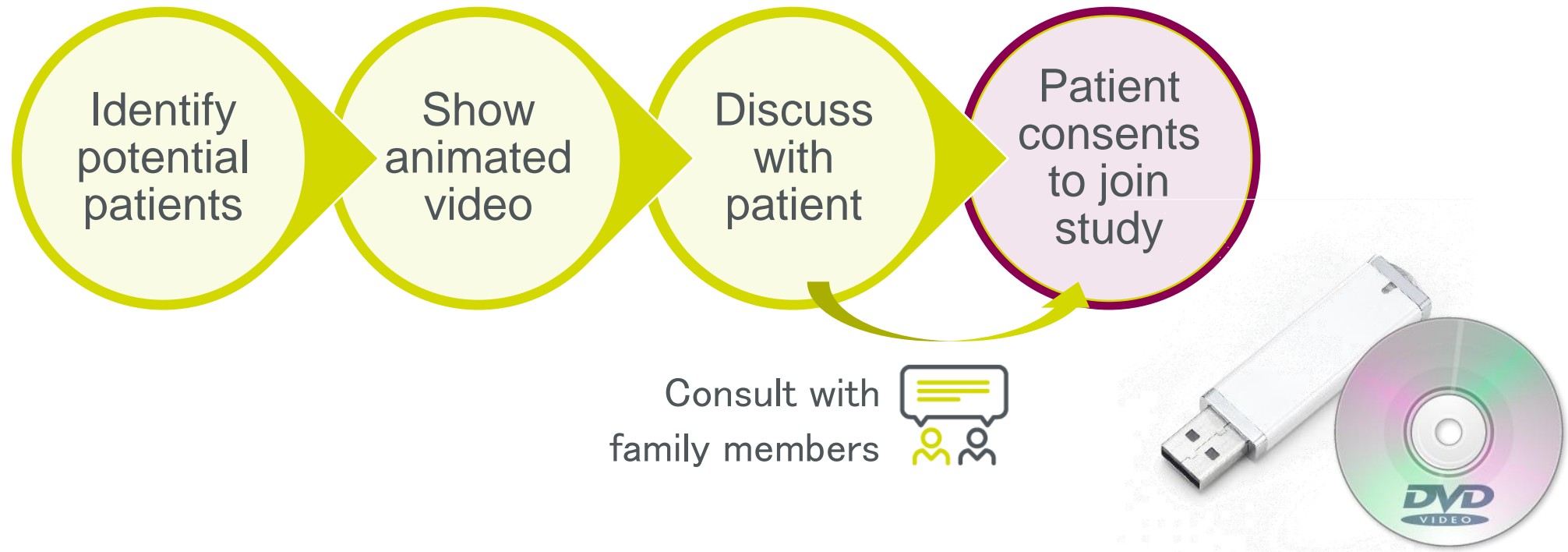
Informed consent with animated video

- Video
- Models
- Animations
- Algorithms running behind video
- Comics for children
- eCONSENT



Informed consent with animated video

Making an informed decision



Virtual trials

Taking the study to the patient

What are virtual trials?

- Virtual/remote/decentralised/site less trials (Ph I-III) or direct-to-patient (DTP) /direct-with-patient (DWP) studies (Ph IV) are designed to make it as easy as possible for patients to participate in clinical research by **taking all or part of the study to them in their homes**



Why virtual trials?

There are currently

>40,000 clinical studies recruiting

in the U.S.



80% delayed due to recruitment problems*



70%

of potential participants **live more than 2 hours** away from their nearest study center, which limits recruitment and retention**



85%



of clinical trials **fail to retain** enough patients

30%



Average dropout rate across all clinical trials***

The plan is to make studies more accessible by deploying a virtual trials service to **reduce the practical, financial and geographical barriers** to participation, thereby achieving better recruitment and retention.

*<http://mediaroom.sanofi.com/sanofi-launches-digital-clinical-trials-to-improve-recruitment-and-reduce-trial-times/#!>

**<https://forteresearch.com/news/infographic-retention-in-clinical-trials-keeping-patients-on-protocols/>

***<https://www.fiercebiotech.com/cro/sanofi-launches-new-virtual-trials-offering-science-37>

Virtual visit



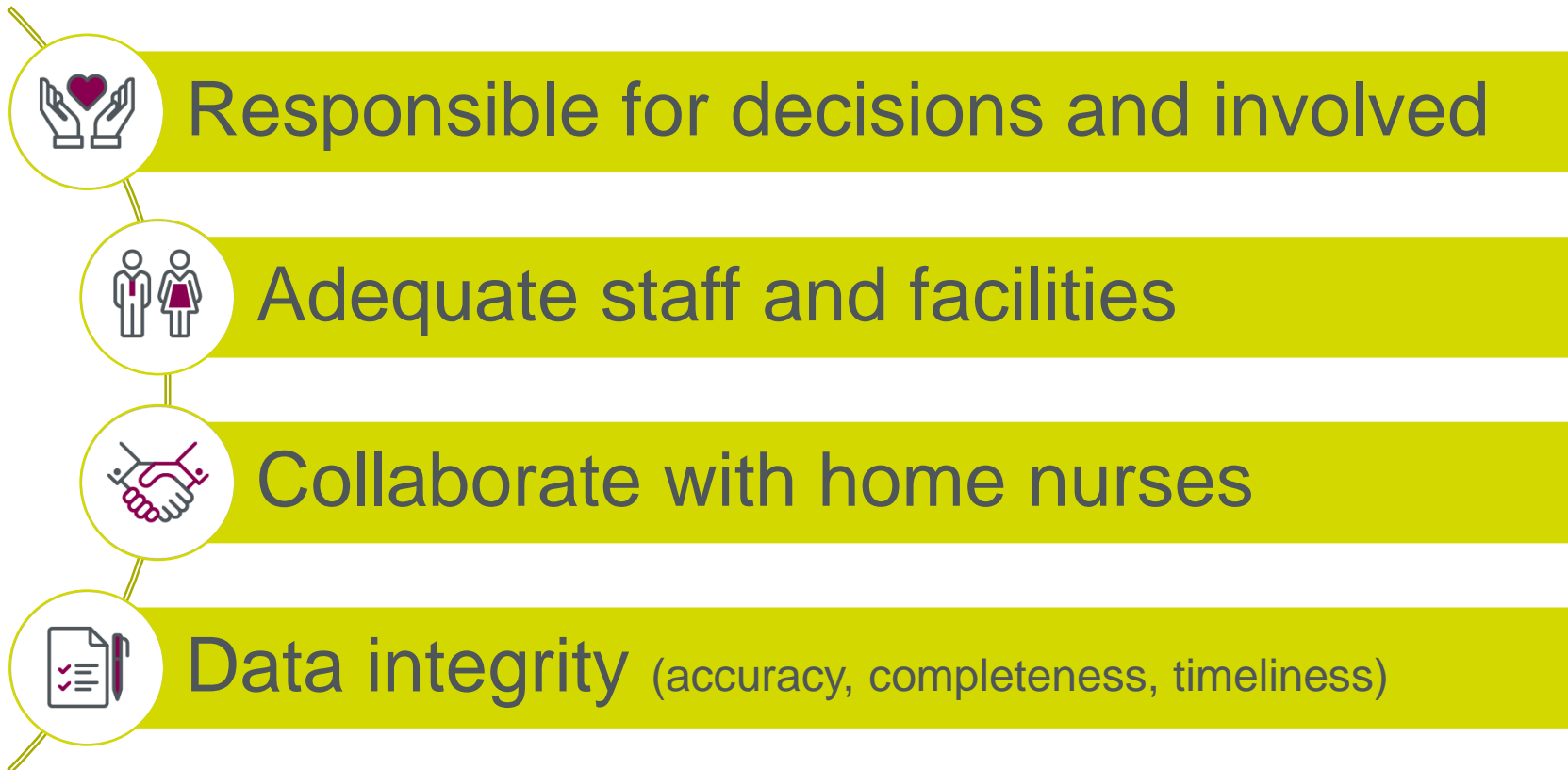
Virtual trials

Home nursing



Ensuring Good Clinical Practice (GCP)

Investigator responsibilities





Simplify the patient journey

So, what does it all mean?

- › Face-time with doctors, self-diagnosis and on-line pharmacy
- › UBER Health, Google health, 23andMe
- › Isolation of patients (MDD) and some actually not wanting nurses to visit them at home
- › Doctors & Nurses air traffic controllers of patient care – ask them at Feasibility





Thank you