

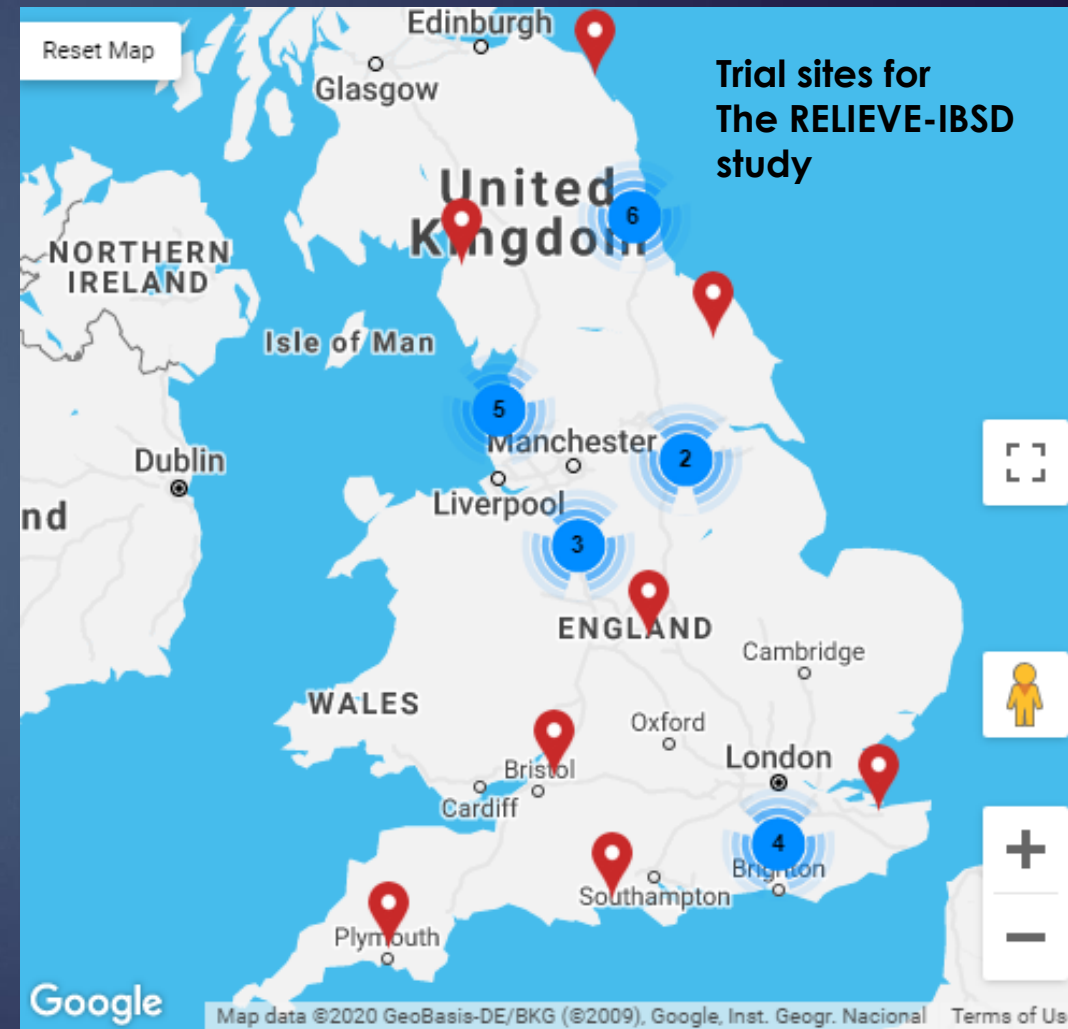
Virtual Trials (and evaluations)

YAN YIANNAKOU

26/2/2020

Clinical Trials and Device Evaluations

...depend on recruiting patients to trial sites



TRITON study

- ▶ 18 months recruitment
- ▶ 14 UK sites
- ▶ £1.5m spent
- ▶ Target = 425
- ▶ Achieved 64



- ▶ Using IBS national registry, social media campaign
 - ▶ > 400 eligible patients identified in 2 months
 - ▶ Only 24 within easy reach of recruiting site

Clinical Trial Performance

Proportion of commercial trial sites failing
to recruit to target*
(even if extended time)

33%

*NIHR Open Data Platform 2019/20

Clinical Trial Performance

Cost of set-up/monitor/close-down a trial site is around*

\$20,000

Proportion of trial sites fail to recruit a single patient**

20%!

*US data

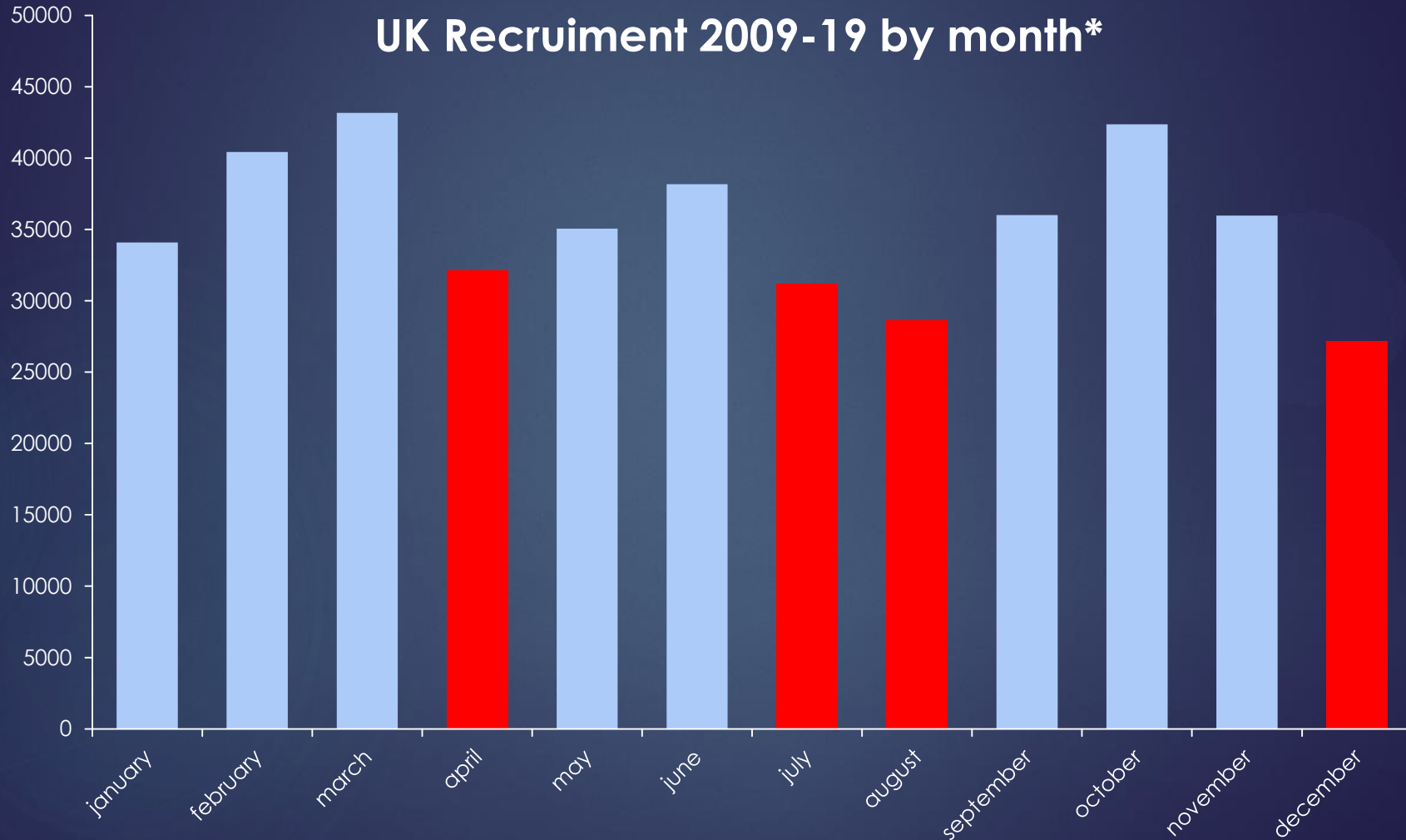
**Pharma Times, June 2019

Clinical Trial Performance

Proportion patients who drop out of
studies

30-40%

Clinical Trial Performance



A system of geographical exclusion

You would never design it like this!

Medical Device Regulations 2019

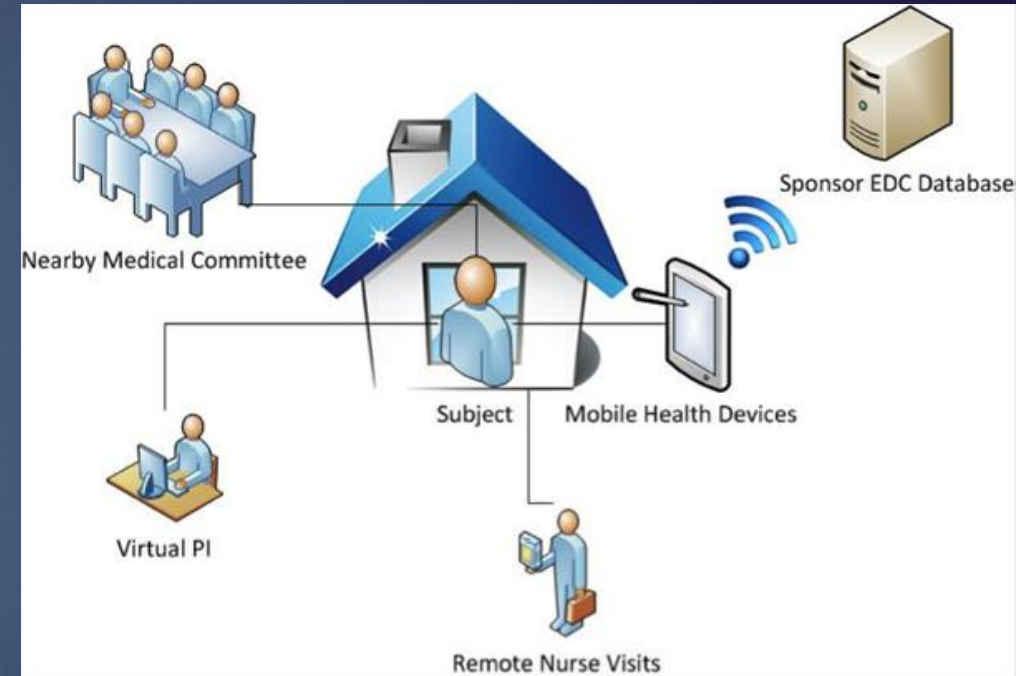
- ▶ On-going clinical evaluation
 - ▶ Efficacy and safety
 - ▶ Objective evidence
 - ▶ Ethically designed
 - ▶ Scientifically valid end-points

How is that achievable on a limited budget?

Virtual trials

10

- ▶ **Trials without recruiting sites**
- ▶ End-to-end digital management
- ▶ Community based recruitment
- ▶ Online consultation and consent
- ▶ Electronic data capture

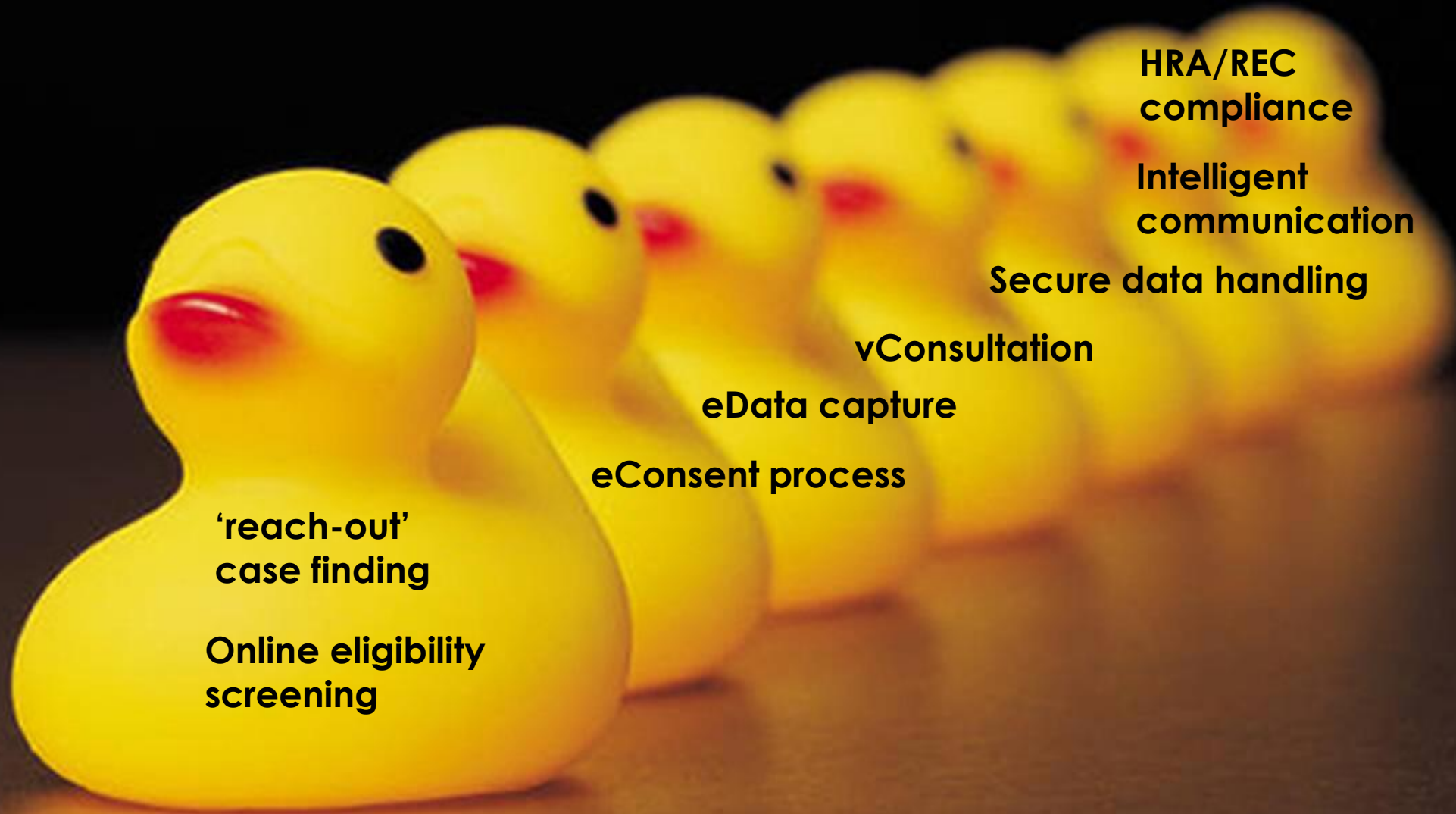


Virtual trials: advantages

- ▶ Quicker / complete recruitment
- ▶ Remove geographical exclusion
- ▶ More generalizable population (real world)
- ▶ Better consent processes
- ▶ Better retention
- ▶ Data is more complete / more meaningful
- ▶ Cost reduction



COMING
Soon
Virtual trials



**'reach-out'
case finding**

**Online eligibility
screening**

eConsent process

eData capture

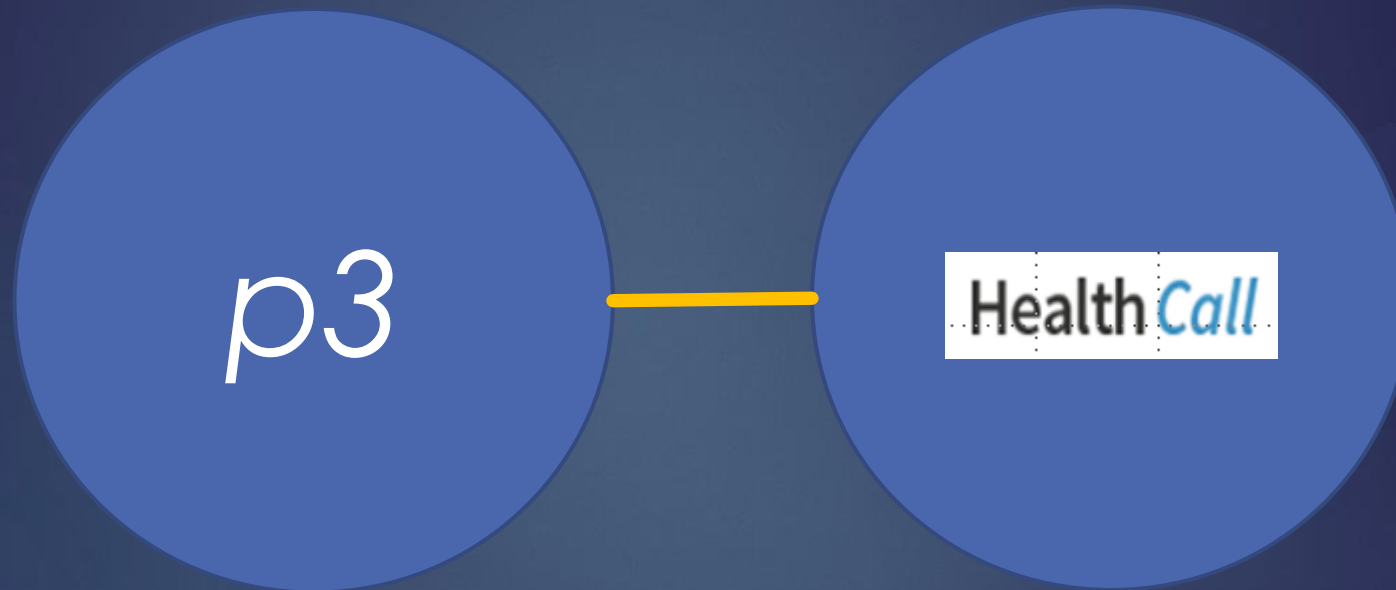
vConsultation

Secure data handling

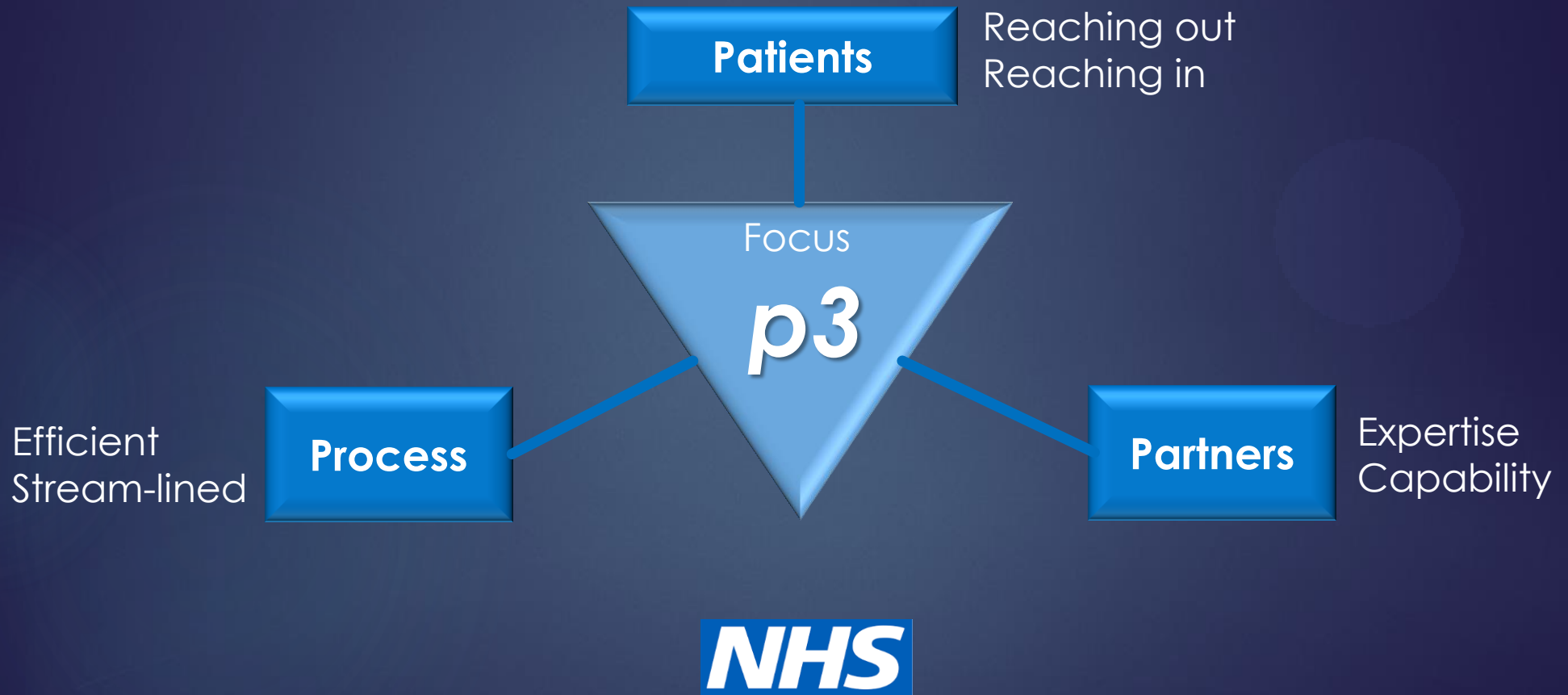
**Intelligent
communication**

**HRA/REC
compliance**

A unique NHS collaboration



A phase 3 commercial trials unit



clinithink

NuTH partners



C4C Registries



ContactME-IBS
Are you interested in participating in research into Irritable Bowel Syndrome?

Visit the website for more information
www.contactme-ibs.co.uk



GP partners



P3 recruitment engine

Community pharmacies



heart
96-103
more music variety



105-106
CAPITAL
FM

THE NORTH EAST'S NO.1 HIT MUSIC STATION

Digital media



Health Call


Digital Health Platform

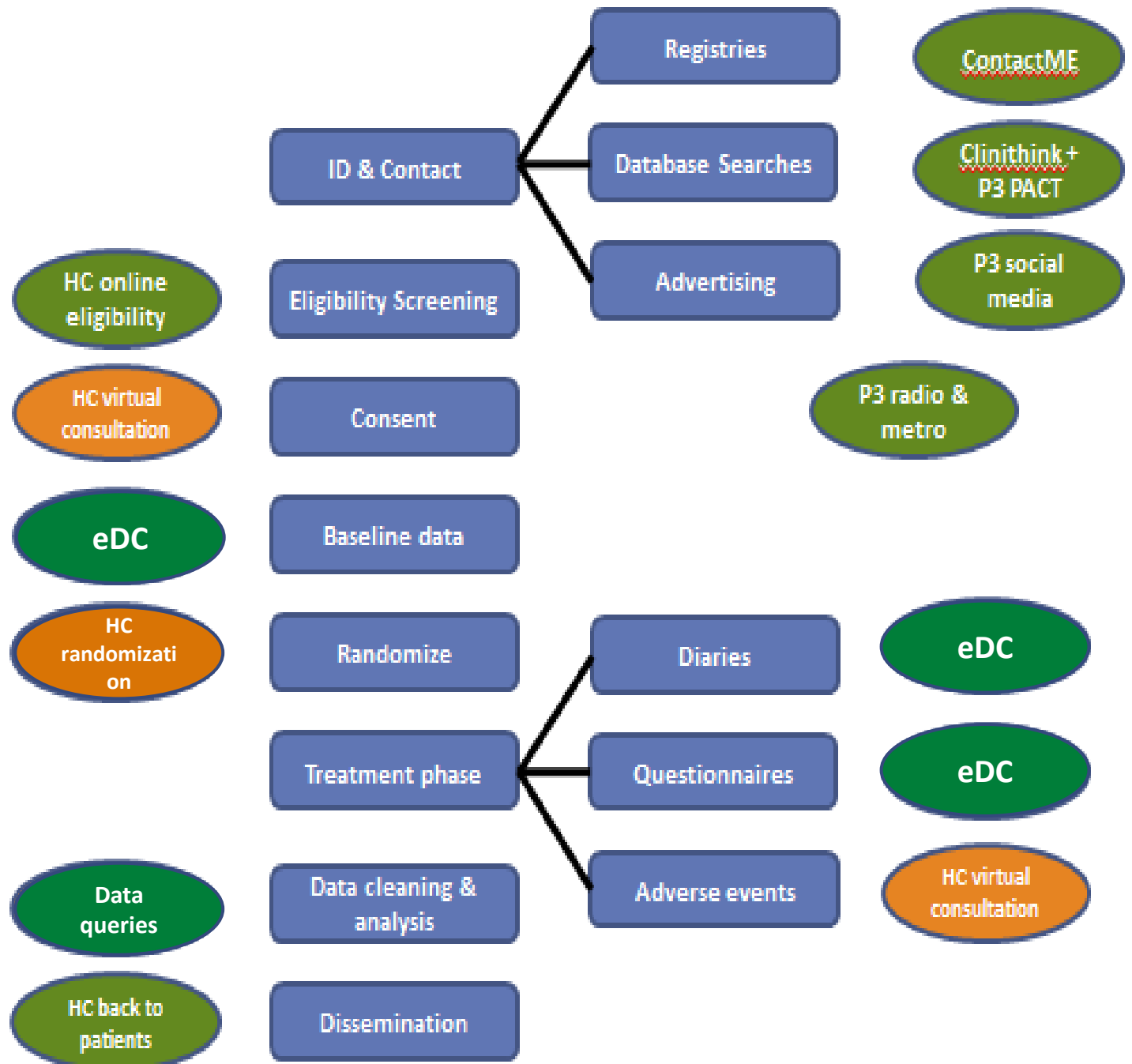


Digital Health Platform



An end-to-end digital trial management platform

-  tested
-  developing
-  theoretical



Imagine if....

There were no geographical barriers to recruitment



Imagine if....

Cost effective device evaluations

- ▶ High quality feedback
- ▶ No data input costs
- ▶ Direct to company results (not clinician)
- ▶ Validated results and analysis



COMING
Soon
Virtual trials

*To a venue
near you*

Interested?

[*Yan.yiannakou@nhs.net*](mailto:Yan.yiannakou@nhs.net)