

Cambridge University Hospitals 
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BRITISH SOCIETY OF
GASTROENTEROLOGY



PROFILE trial

*PR*edicting *O*utcomes *F*or *C*rohn's
*d*isease using a *m*o*L*ecular *b*iomark*E*r

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Conflicts of interest

- I declare educational grants, travel grants and/or speaker fees from Celltrion, Dr Falk Pharma, Galapagos, Janssen, Lilly, Pfizer, Pharmacosmos, SBK Healthcare, Takeda and Tillotts Pharma AG

Results reveal...



LOCAL NEWS >

The 5 Countries With The Most Expensive Beer In The World

Brief for today

How do we deliver more successful IBD investigator-initiated trials from the UK?

What were the secrets to success in PROFILE? Can you give us your tips and tricks?



RCTs are critical to shape healthcare policy, guidelines, and change clinical practice

The NEW ENGLAND JOURNAL of MEDICINE

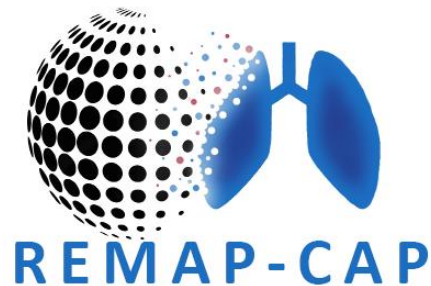
SOUNDING BOARD

The Magic of Randomization versus the Myth of Real-World Evidence

Rory Collins, F.R.S., Louise Bowman, M.D., F.R.C.P., Martin Landray, Ph.D., F.R.C.P.,
and Richard Peto, F.R.S.

Not so long ago...

Getting results: why NHS clinical trials are the envy of the world



AstraZeneca and Pfizer/BioNTech saved over 12 million lives in the first year of vaccination

But in just the space of a few years...

The Guardian view Columnists Cartoons Opinion videos Letters

Opinion
Medical research

Britain's Covid research led the world -
why have our clinical trials fallen off a cliff?
Andrew Pollard

Wed 26 Apr 2023 10.01 BST



128

Pressures on the NHS, a lack of doctors and post-Brexit delays
are hampering our ability to develop cutting-edge drugs



Independent report

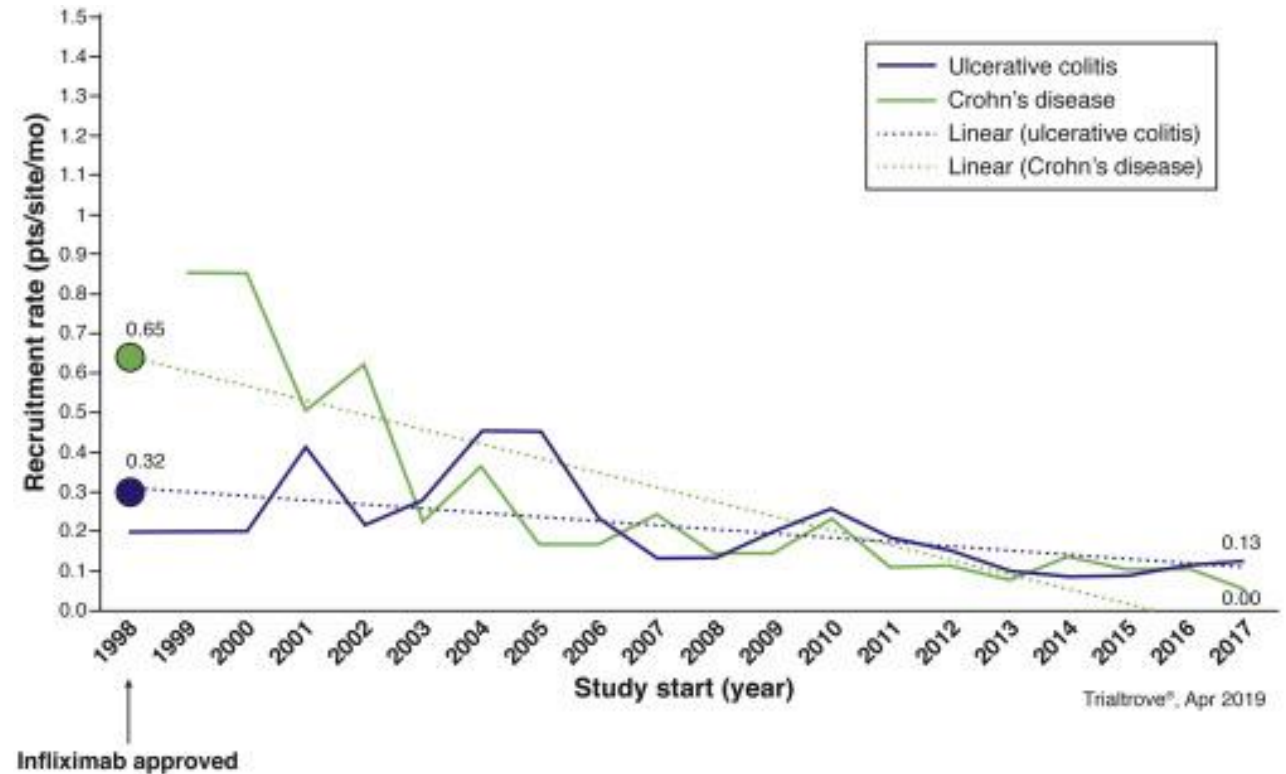
Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report

Published 25 May 2023

Getting harder to deliver IBD trials

Declining Enrolment and Other Challenges in IBD Clinical Trials: Causes and Potential Solutions [Get access >](#)

Mathieu Uzzan ✉, Yoram Bouhnik, Maria Abreu, Harris A Ahmad, Shashi Adsul, Hilde Carlier, Marla Dubinsky, Matthew Germinaro, Vipul Jairath, Irene Modesto, Eric Mortensen, Neeraj Narula, Ezequiel Neimark, Alessandra Oortwijn, Marijana Protic, David T Rubin, Young S Oh, Jolanta Wichary, Laurent Peyrin-Biroulet, Walter Reinisch



Uzzan M et al. JCC 2023

Harris MS et al. Gastro 2019

My lessons learned from PROFILE

- How do you put together a **winning team** to deliver a clinical trial?
- What are **key factors** to help determine “**success**”?
- What are **major pitfalls** to watch out for?
- How do we **move forward as a field** – to deliver the IBD clinical trials of the future?

Steps to success 1 - Brains



IT'S BIG

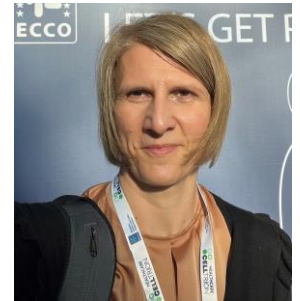
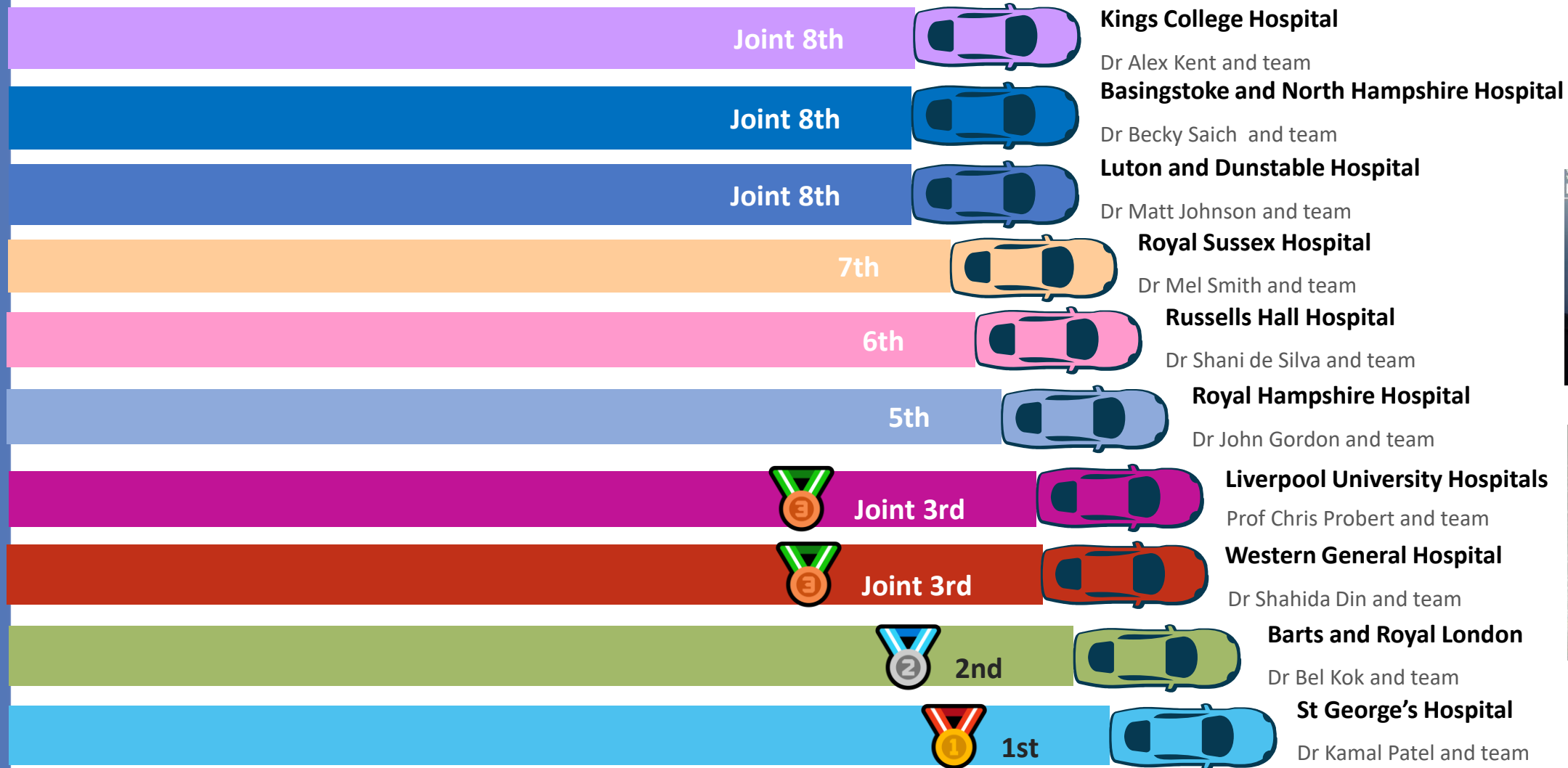


What's more important than brains?



Steps to success 2 – great teams

*not to scale



Research for all...not ivory tower research



Leadership more important than brains or brawn?

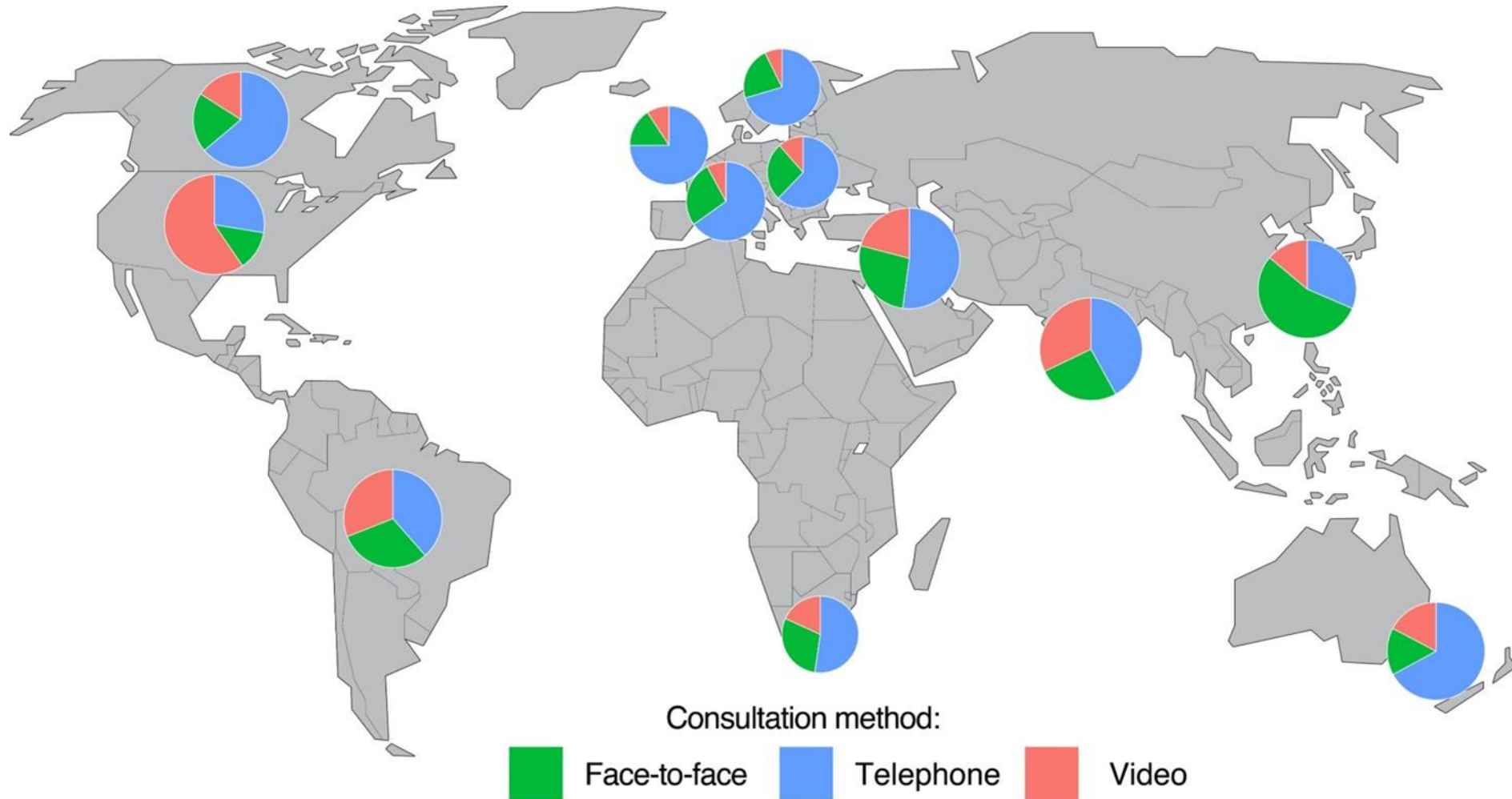


Steps to success 4 – Work closely with patients & patient organisations

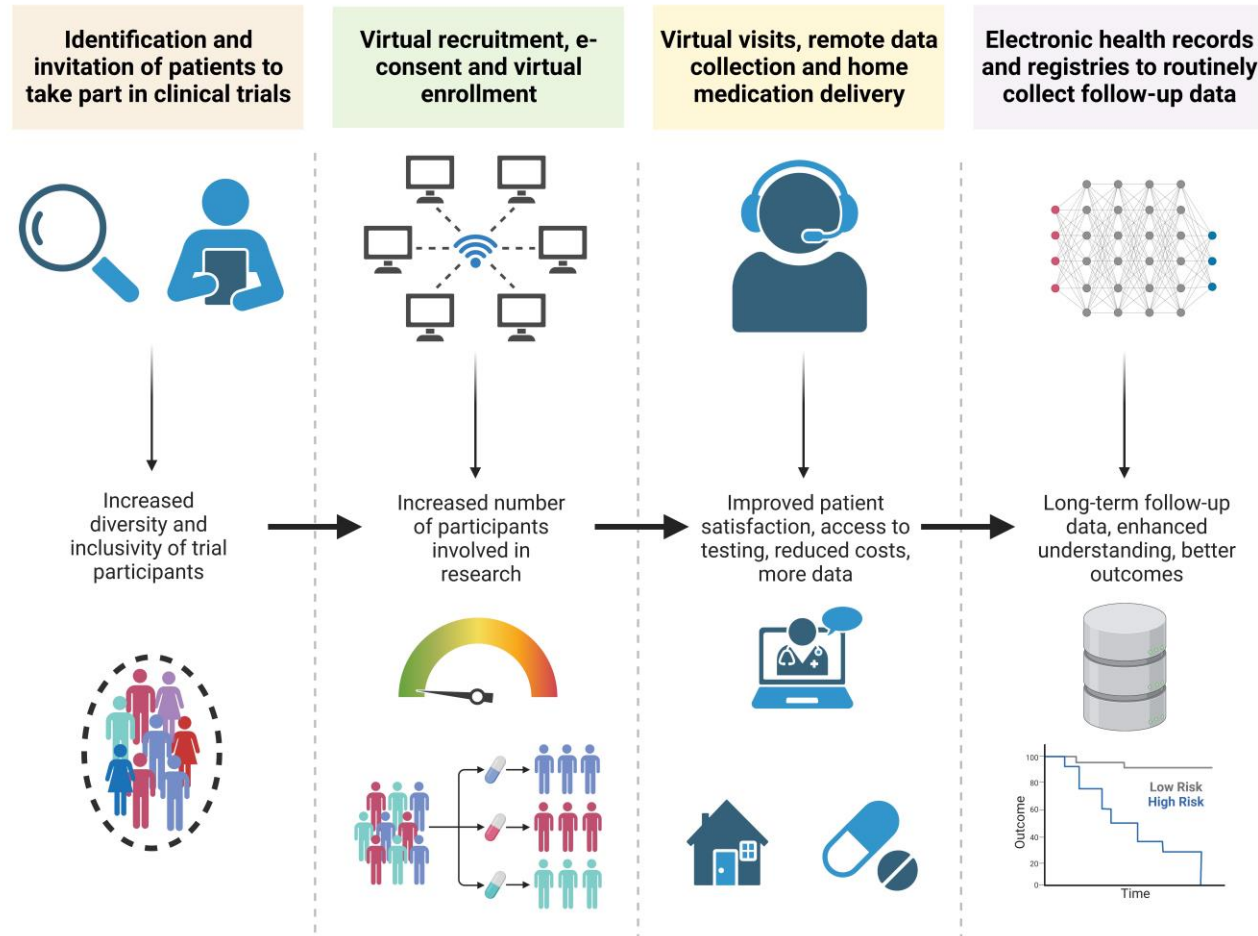
**CROHN'S &
COLITIS UK**



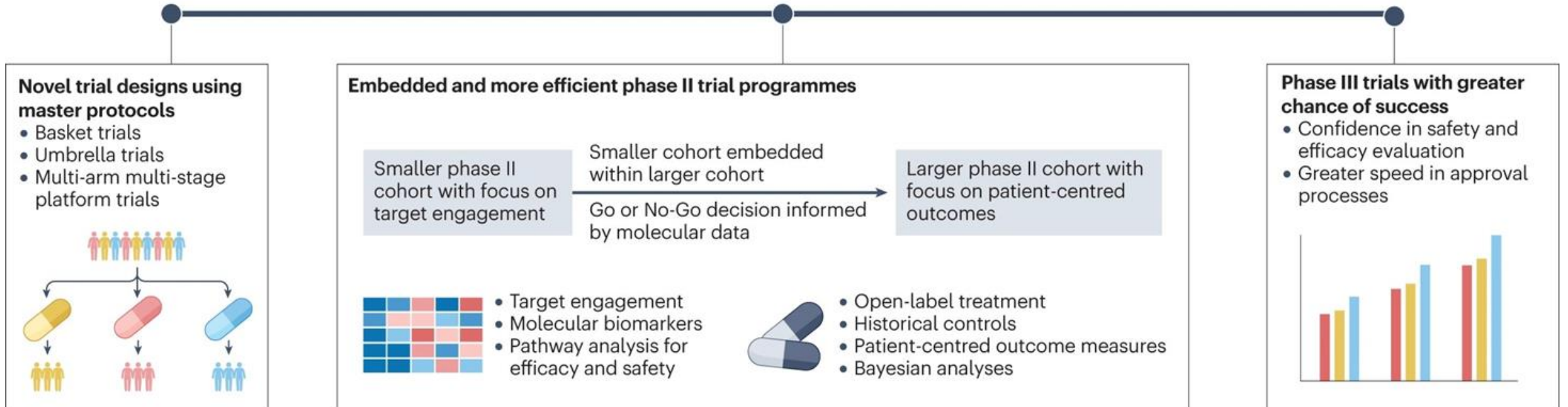
Healthcare changed forever since pandemic



Steps to success 5 – Embrace new ways of delivering trials



Steps to success 5 – Embrace new ways of designing trials



Steps to success 6 – Support and provide opportunities to next generation of PIs

NIHR National Institute for Health Research

Associate Principal Investigator Scheme

Now registering in:

- Cancer
- Gastroenterology
- Surgical
- Ear, Nose and Throat
- Hepatology

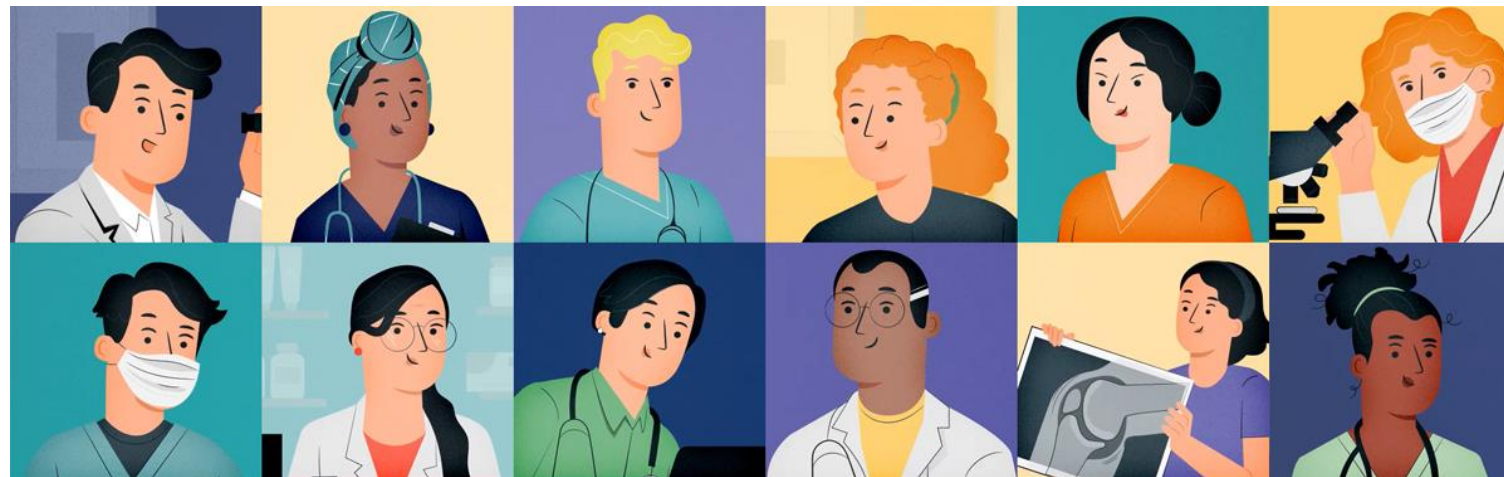
nature reviews gastroenterology & hepatology

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World View | [Published: 17 January 2022](#)

Developing a cadre of clinician trialists in gastroenterology and hepatology



Conclusions

- **RCTs are crucial** to influence healthcare policy, guidelines and practice
- **Academic (investigator-initiated) trials** are the bedrock for any speciality - incredibly hard to deliver but critical to determine optimal treatment strategies
- PROFILE is **a huge success story for UK (and global) IBD community**
- To deliver trials like PROFILE **you need brains, you need brawn, but most importantly you need great leadership**
- We need to embrace **innovations to deliver the IBD clinical trials of the future** (and provide opportunities to develop a cadre of academic IBD trialists)

HUGE success story for IBD community

