Supporting COVID-19 research

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Health Research Authority

HRA Board | 20 May 2020

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Strategy

Our work to support COVID-19 research aims to:

- enable high-quality COVID-19 research projects to start as quickly as possible
- ensure public visibility of approved studies
- support our volunteers in reviewing studies by providing good technology, training and support
- seize the opportunities gained from this way of working to adapt our business model

This presentation is structured around these aims, but before that, let’s look at how COVID-19 has affected our approvals activity

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Effect on our approval activity

- The total number of **new applications** for review has reduced by approximately 30%
- This is made up of a reduction in student research applications (we no longer review non-PhD student research) and a reduction in non-COVID-19 research applications
- COVID-19 studies make up around 40% of all new applications
- The total number of **amendments** has reduced by approximately 30%
- COVID-19 studies need experienced Approvals Specialists and input from senior staff. Although our approvals staff capacity is slightly reduced, the reduction in overall application numbers means we can manage current workloads.

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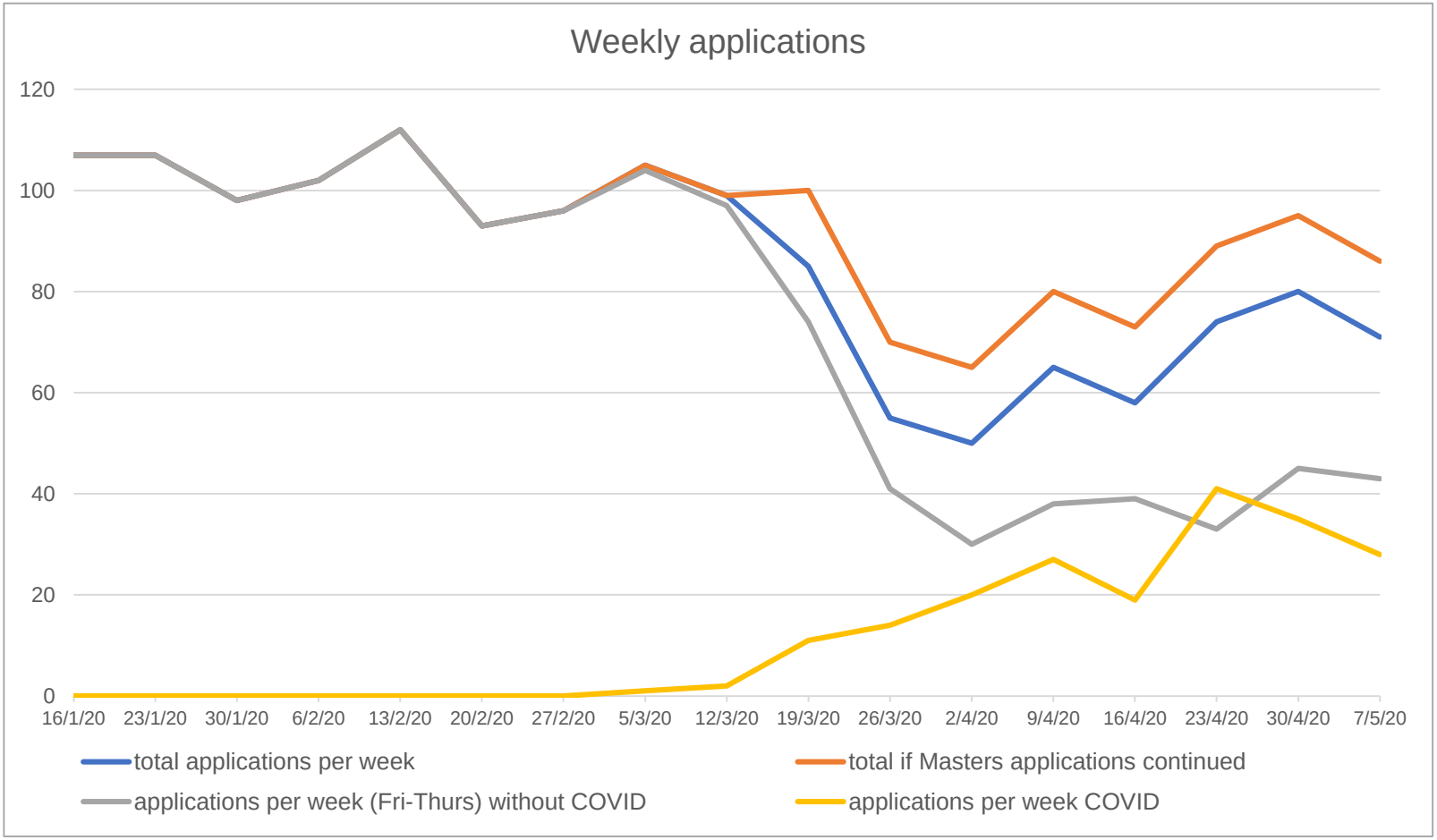
New applications for review



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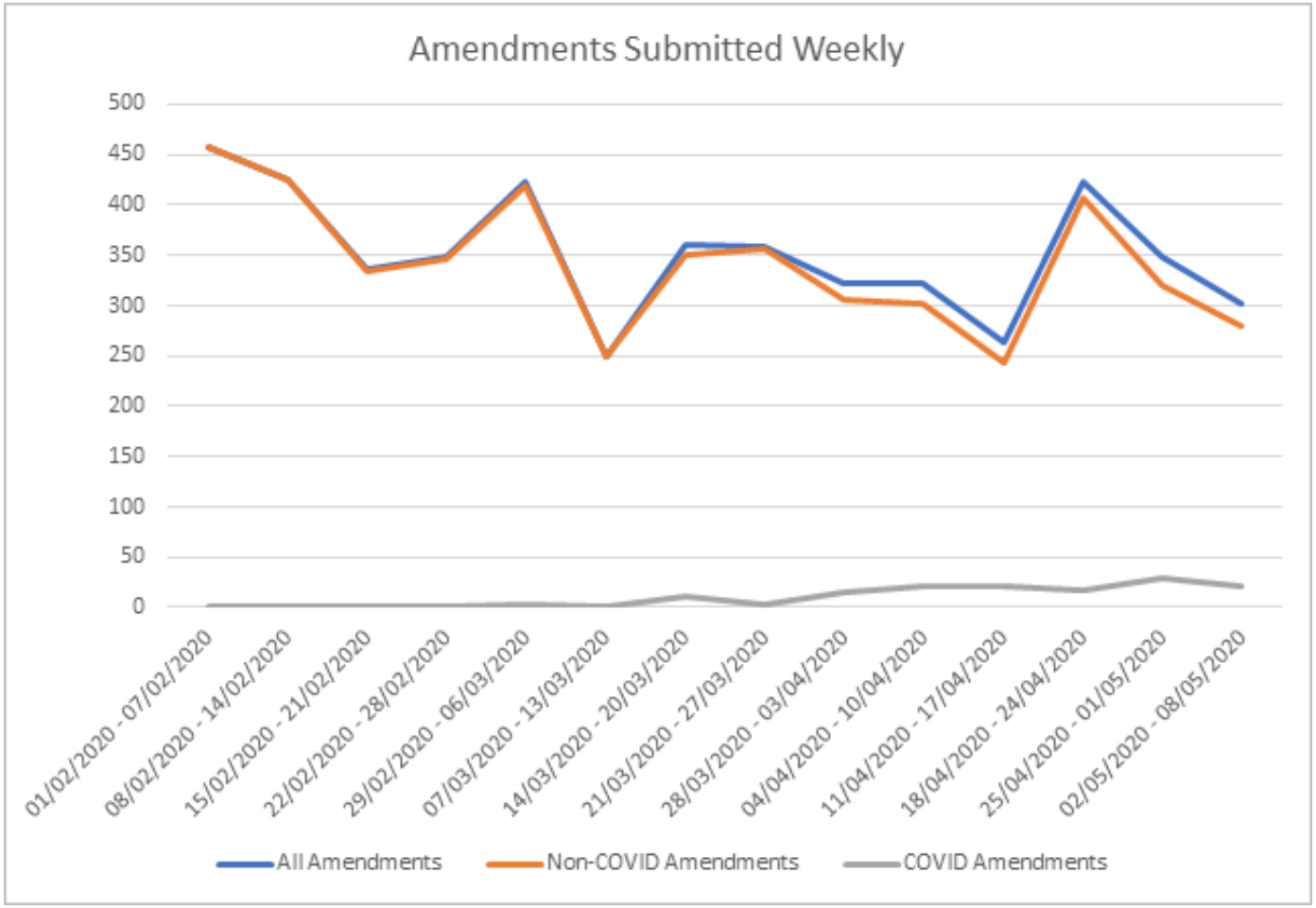
Amendments



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Enabling research

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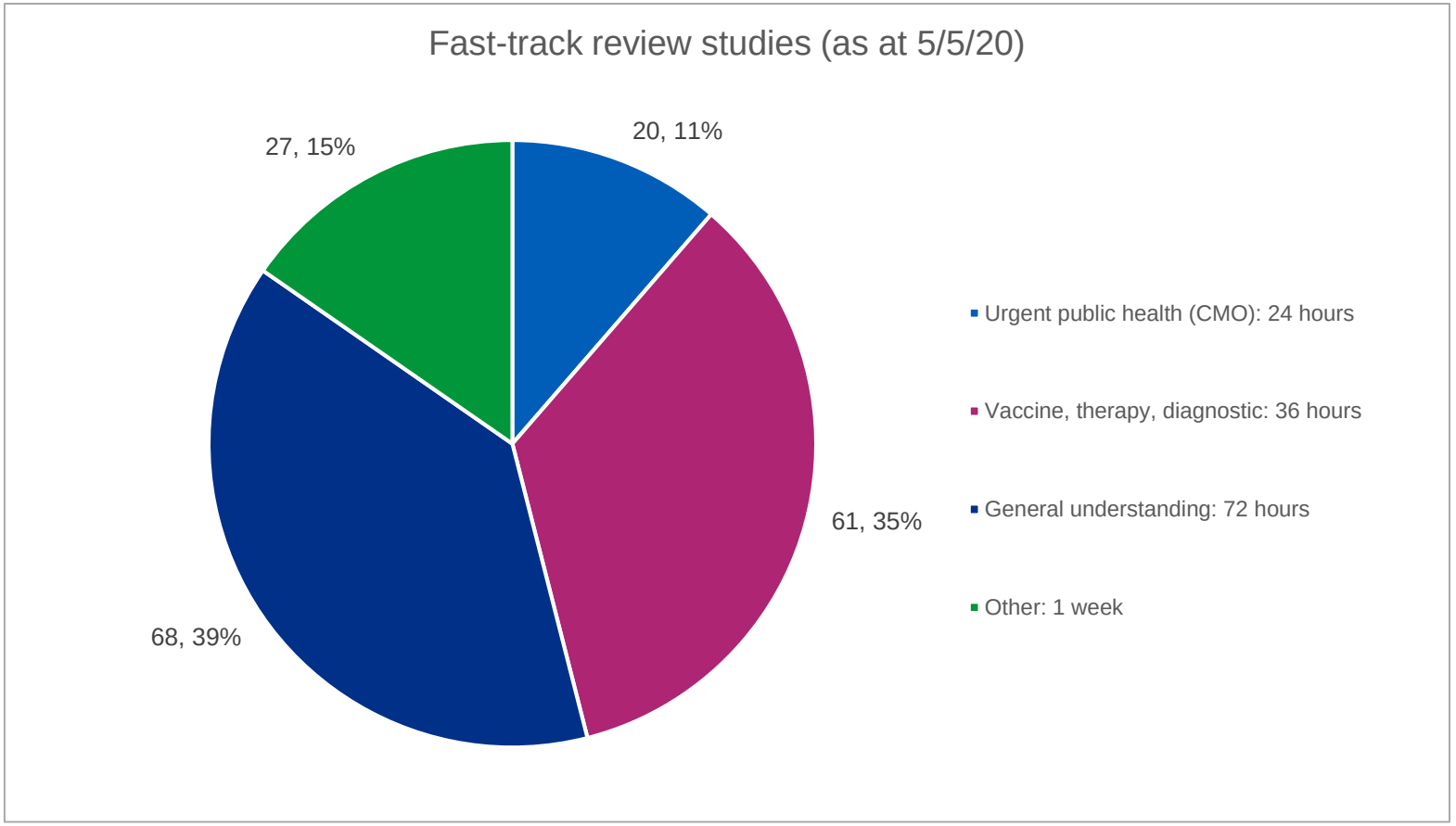
What have we reviewed?



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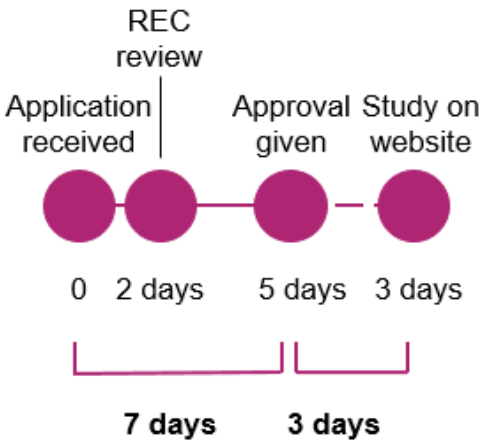
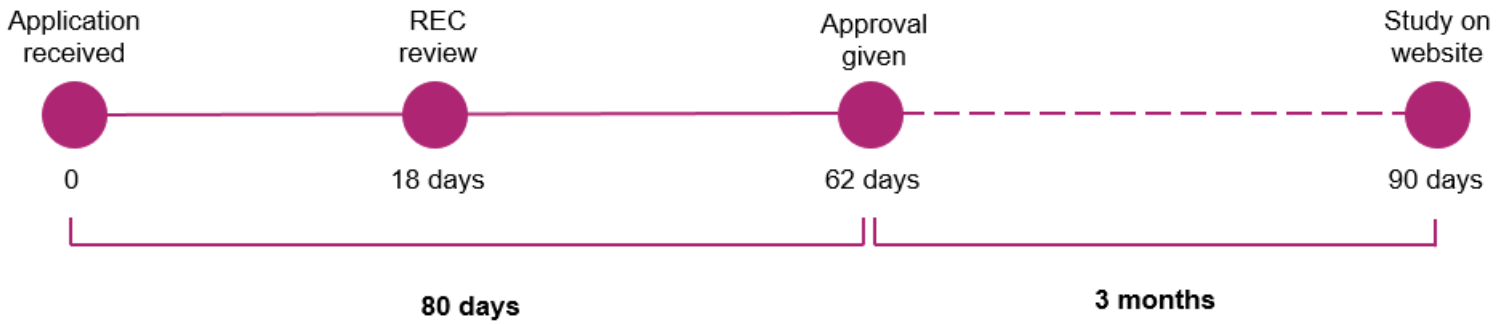
How do timelines compare?

COVID-19 fast-track review



Standard review



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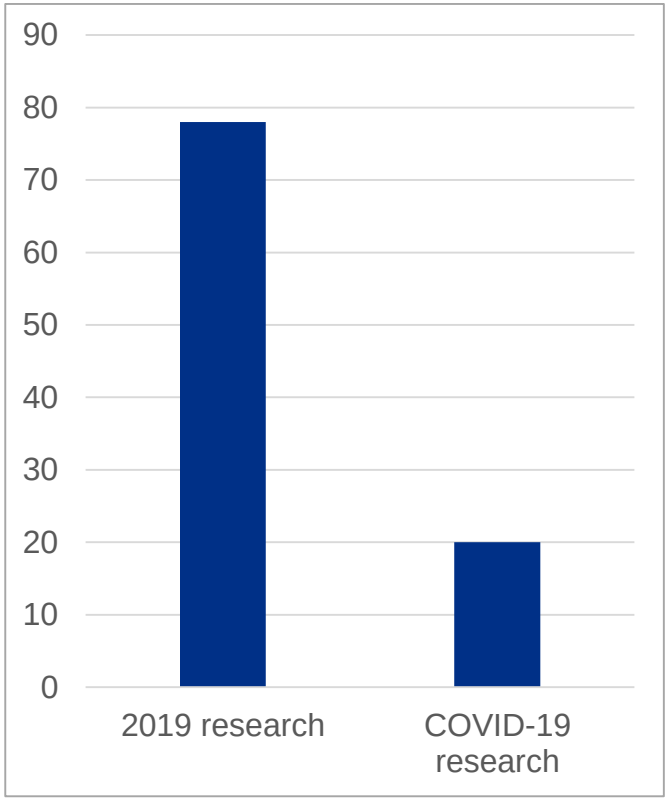
Supporting public involvement

- Besides speed of review, we're also focussing on good research practice, particularly public involvement
- In the first 40 COVID-19 research studies, only 20% had involved patients, carers, service users, or other members of the public in their research (compared to 78% last year)
- We are working with the community to launch a service to signpost researchers to patients and the public who can review studies in 24-48 hours
- This will make for more ethical research and help with recruitment and retention



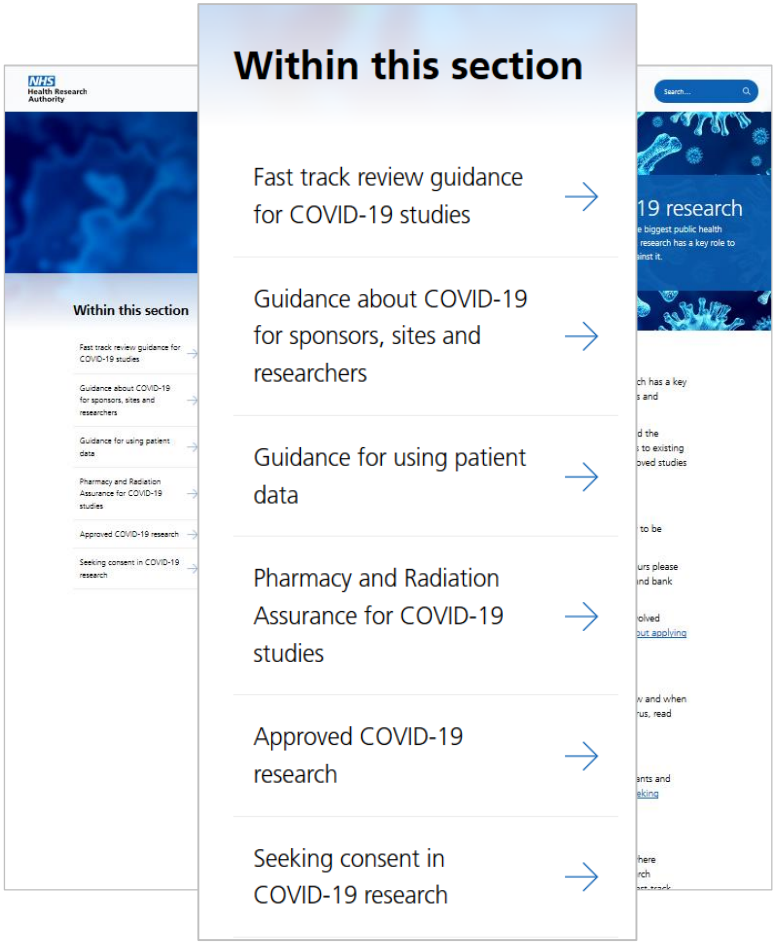
Click to download csv file of the data.

Guidance and advice for researchers

A dedicated section of the website help researchers understand:

- How to apply for fast-track review
- How to manage existing studies to minimise amendments
- How the law around consent in adults lacking capacity works
- How to seek support for us of patient data without consent

We're also providing bespoke advice and support for the NHS Nightingale hospitals, Genomics England, the ACCORD2 study



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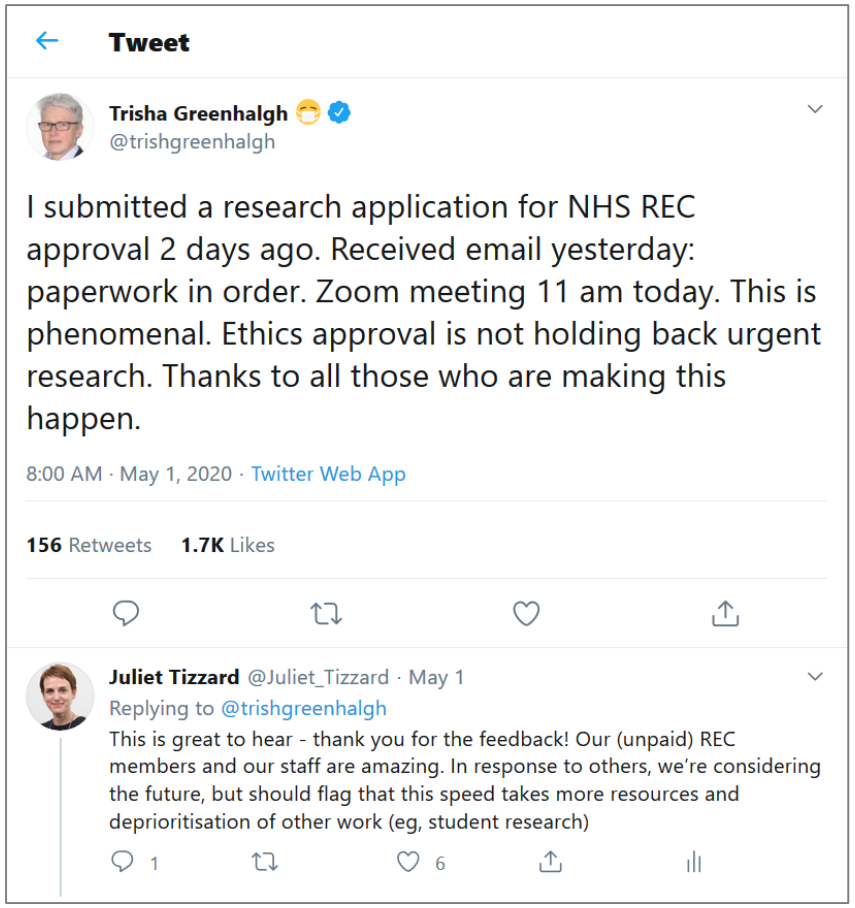
Impact: our service for applicants

- Individual feedback is very positive
- User satisfaction is up from 55% early in the year to 80% in April

"Thank you, thank you, thank you – advice, clear proportionate guidance on website, speed, calling me back … amazing service… very helpful."



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Impact: our communications

Website

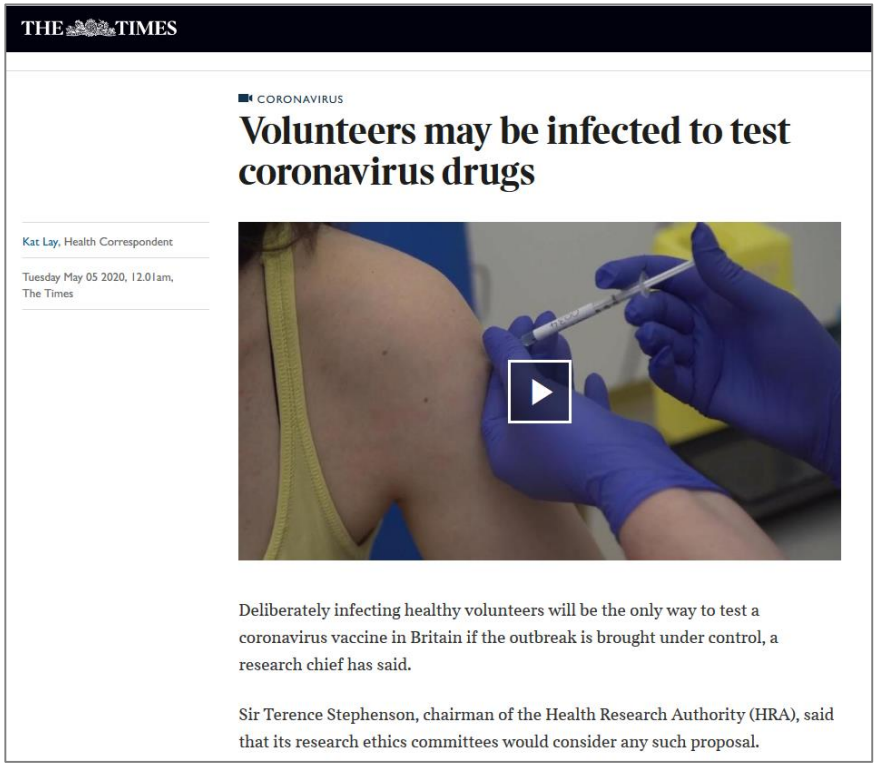
- Number of visits up by 25%
- 25% of visitors going to COVID-19 section, which has good engagement

Media

55 media mentions, including The Times, Daily Mail, BMJ, Nursing Times

Social media

- 80% increase in views
- 200% increase in retweets
- 259% increase in likes
- 995% increase in top engagement for one tweet (26,000 people)



THE TIMES

CORONAVIRUS

Volunteers may be infected to test coronavirus drugs

Kat Lay, Health Correspondent

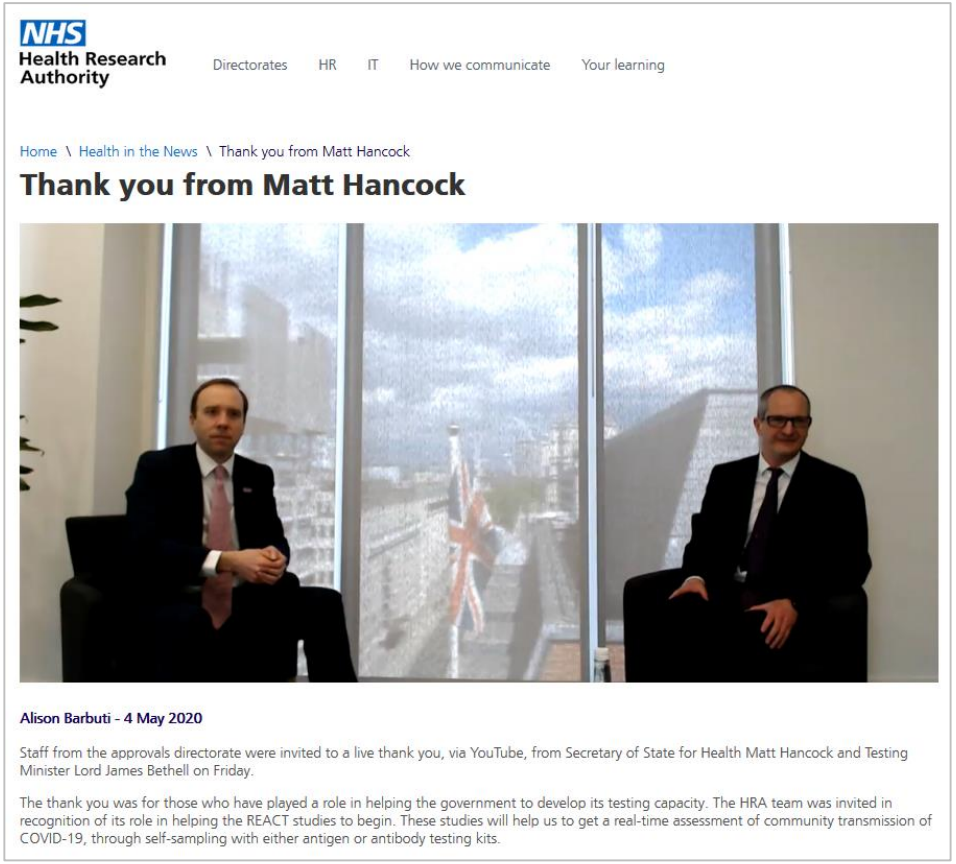
Tuesday May 05 2020, 12.01am, The Times

Deliberately infecting healthy volunteers will be the only way to test a coronavirus vaccine in Britain if the outbreak is brought under control, a research chief has said.

Sir Terence Stephenson, chairman of the Health Research Authority (HRA), said that its research ethics committees would consider any such proposal.

Impact: our help to the system

- Working with other regulators to support fast regulatory approvals
- Assisting with site set-up
- Providing pharmacy and radiation assurances
- Taking a proportionate approach (for example, on amendments) aligned with MHRA
- This work is being recognised



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Directorates HR IT How we communicate Your learning

Home \ Health in the News \ Thank you from Matt Hancock

Thank you from Matt Hancock

Alison Barbuti - 4 May 2020

Staff from the approvals directorate were invited to a live thank you, via YouTube, from Secretary of State for Health Matt Hancock and Testing Minister Lord James Bethell on Friday.

The thank you was for those who have played a role in helping the government to develop its testing capacity. The HRA team was invited in recognition of its role in helping the REACT studies to begin. These studies will help us to get a real-time assessment of community transmission of COVID-19, through self-sampling with either antigen or antibody testing kits.

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Creating public visibility

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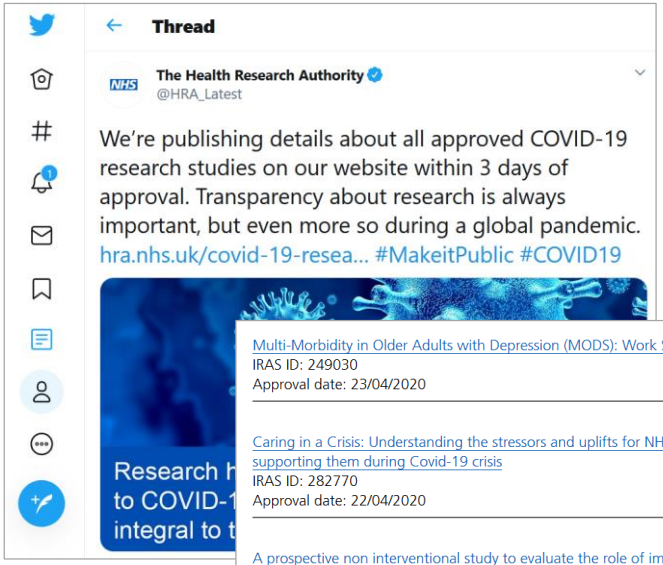
Information about approved studies

- Details of all COVID-19 studies and amendments published within three days of approval
- Each study is listed with key details such as the type of study and the research summary.
- If a study is an urgent public health research study this is listed



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Supporting volunteers

Moving to virtual working

- All 65 RECs have moved to virtual meetings, enabled by existing online access to study documents
- Short timelines has meant running 17 ad hoc meetings with 87 members (116 attendances)
- Training (also done via Zoom) on chairing virtual meetings and ethical issues in public health emergency research

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Seizing the opportunity

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What we already know

- Our work to create an integrated structure and team resilience in Approvals has paid off
- The combined review of clinical trials of medicines (CWoW) work with MHRA has helped, even for non-CWoW studies
- Our use of technology and existing remote working approaches has enabled us to flick to new ways of working overnight
- Our volunteers are committed to working in this way to help the national effort
- We've been able to speed up some changes, such as use of the Member Portal, that would have otherwise taken some time
- New formats encourage more cross-cover between RECs and greater learning and consistency

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What we need to consider

- What should we retain of remote working in future?
- Should we consider prioritising certain types of studies for faster review in future? Or push ahead on streamlining review of all studies and applying proportionality more?
- If the former, what criteria should we use and how shall we determine them? What resources do we need to apply those criteria fairly?
- Whilst speeding up of our approvals is a clear goal, how can we influence study set-up, where delays and complexity is more present?