



# MHRA Update, December 2021

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Medicines & Healthcare products Regulatory Agency

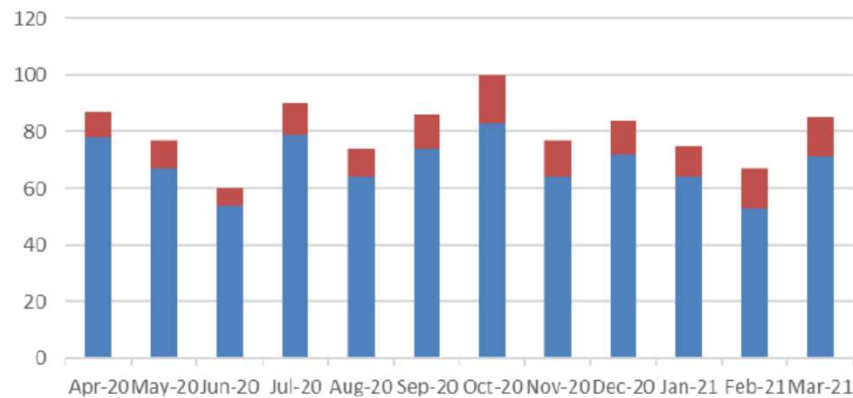
# Agenda

- Metrics
- Novel trials and COVID
- Brief ILAP update
- Combined review from January 2022
- CTR and impact in UK
- Legislation update

# Metrics

<https://www.gov.uk/government/publications/clinical-trials-for-medicines-authorisation-assessment-performance>

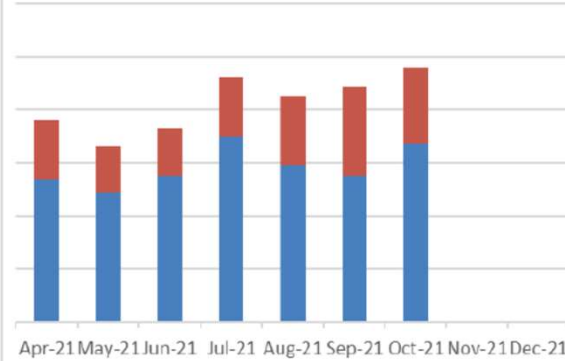
All Initials Assessed



	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21
CTAs Submitted through Combined Ways of Working (CWoW) Process	9	10	6	11	10	12	17	13	12	11	14	14
Standard CTAs	78	67	54	79	64	74	83	64	72	64	53	71

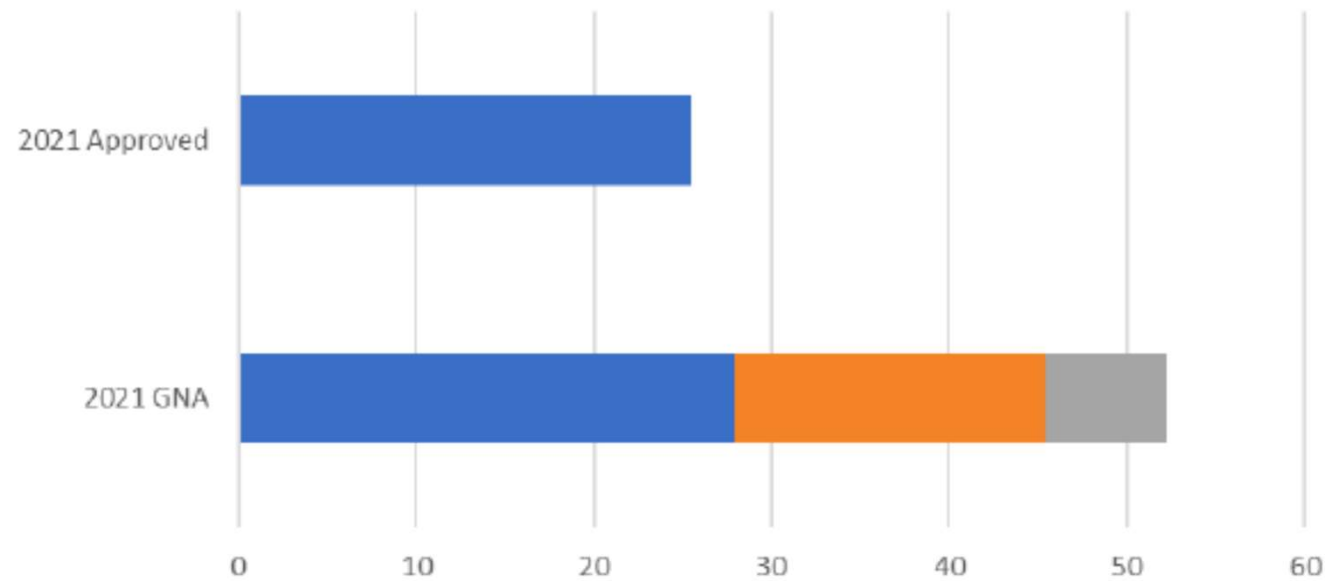
■ Standard CTAs ■ CTAs Submitted through Combined Ways of Working (CWoW) Process

All Initials Assessed



Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21
22	17	18	22	26	34	29		
54	49	55	70	59	55	67		

### Clinical Trial Assessment Performance Phases 2-4

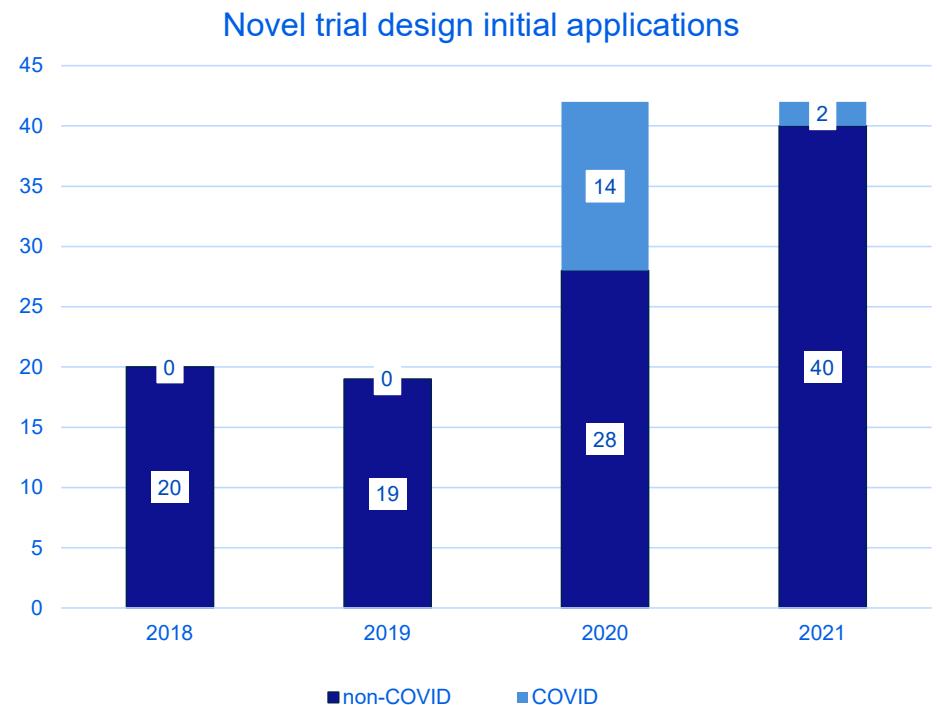


	2021 GNA	2021 Approved
■ Average of 1st Review	27.89	25.44
■ Average of Time Awaiting GNA response	17.56	
■ Average of 2nd Review	6.79	

■ Average of 1st Review    
 ■ Average of Time Awaiting GNA response    
 ■ Average of 2nd Review

# Metrics – novel trial designs, inc. COVID-19

- MHRA CTU has been tracking these trials since January 2018.
- COVID-19 saw a rise in submissions – supported by NIHR and Chief Medical Officer
- Recovery
- Principle
- REMAP-CAP
- Others.....



# Lots of information...

## Managing clinical trials during Coronavirus (COVID-19) - GOV.UK ([www.gov.uk](http://www.gov.uk))

The screenshot shows the GOV.UK website interface. At the top is the GOV.UK logo and a search bar. Below the search bar are navigation links: Departments, Worldwide, How government works, Get involved, Consultations, Statistics, and News and communications. A dark blue banner contains two links: '→ Coronavirus (COVID-19) | National lockdown: stay at home' and '→ Brexit | Check what you need to do'. Below the banner is a breadcrumb trail: 'Home > Clinical trials and investigations'. The main heading is 'Guidance Managing clinical trials during Coronavirus (COVID-19)'. Below this is a sub-heading: 'How investigators and sponsors should manage clinical trials during COVID-19'. A metadata section lists: 'From: Medicines and Healthcare products Regulatory Agency', 'Published: 19 March 2020', and 'Last updated: 17 February 2021, see all updates'. A 'Contents' section lists 15 items, including 'Managing ongoing and halted trials', 'Submitting paperwork for trials which have been halted or are proposed to be restarted', 'Management of COVID-19 vaccine deployment for ongoing non-COVID-19 clinical trials', 'Providing investigational medicinal product (IMP) to trial participants', 'Accountability of Investigational Medicinal Products (IMP)', 'Remote monitoring for trials', 'Changes to the number and type of participant monitoring visits', 'Dear Investigator Letters', 'Reporting of serious adverse events (SAEs), suspected unexpected serious adverse reactions (SUSARs), and submission of annual safety reports (DSURs)', 'Protocol deviations and serious breaches', 'Protocol waivers', 'Urgent Safety Measures', 'Participant safety', and 'Signatures'. A 'Related content' section lists four links: 'Clinical trials for medicines: manage your authorisation, report safety issues', 'Clinical trials for medicines: apply for authorisation in the UK', 'Clinical trials applications for Coronavirus (COVID-19)', and 'MHRA regulatory flexibilities resulting from coronavirus (COVID-19)'. A 'Good clinical practice for clinical trials' link is also present. At the bottom, a 'Collection' section lists 'MHRA guidance on coronavirus (COVID-19)'.

GOV.UK

Search on GOV.UK

Departments Worldwide How government works Get involved  
Consultations Statistics News and communications

→ **Coronavirus (COVID-19)** | National lockdown: stay at home  
→ **Brexit** | Check what you need to do

[Home](#) > [Clinical trials and investigations](#)

Guidance

## Managing clinical trials during Coronavirus (COVID-19)

How investigators and sponsors should manage clinical trials during COVID-19

From: [Medicines and Healthcare products Regulatory Agency](#)  
Published: 19 March 2020  
Last updated: 17 February 2021, see all updates

Contents

- Managing ongoing and halted trials
- Submitting paperwork for trials which have been halted or are proposed to be restarted
- Management of COVID-19 vaccine deployment for ongoing non-COVID-19 clinical trials
- Providing investigational medicinal product (IMP) to trial participants
- Accountability of Investigational Medicinal Products (IMP)
- Remote monitoring for trials
- Changes to the number and type of participant monitoring visits
- 'Dear Investigator' Letters
- Reporting of serious adverse events (SAEs), suspected unexpected serious adverse reactions (SUSARs), and submission of annual safety reports (DSURs)
- Protocol deviations and serious breaches
- Protocol waivers
- Urgent Safety Measures
- Participant safety
- Signatures

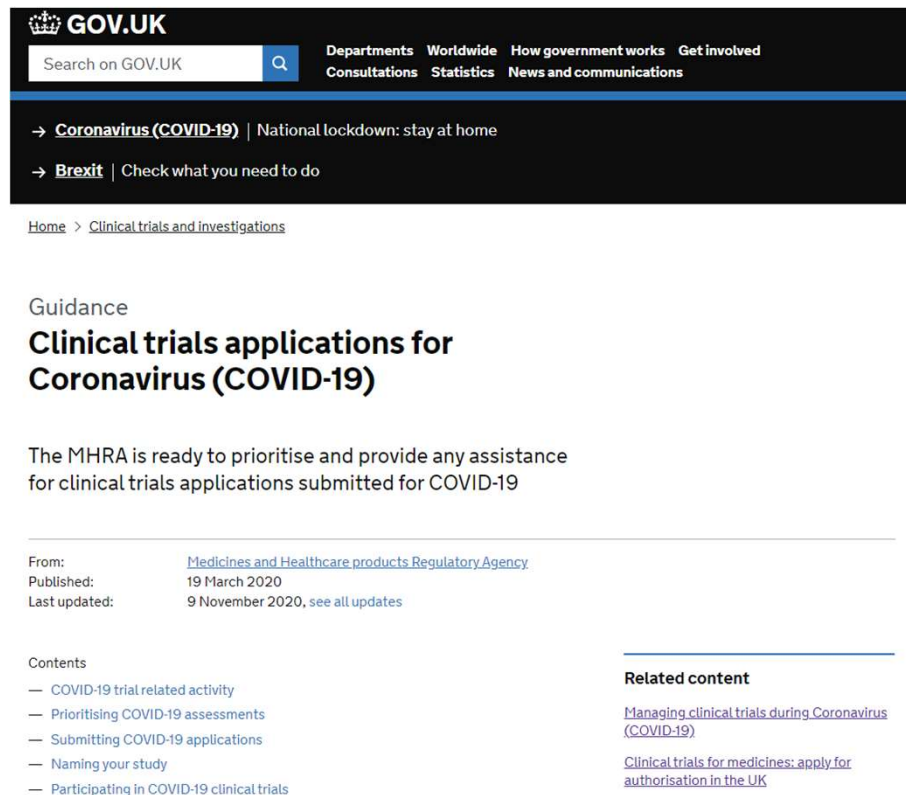
Related content

- [Clinical trials for medicines: manage your authorisation, report safety issues](#)
- [Clinical trials for medicines: apply for authorisation in the UK](#)
- [Clinical trials applications for Coronavirus \(COVID-19\)](#)
- [MHRA regulatory flexibilities resulting from coronavirus \(COVID-19\)](#)
- [Good clinical practice for clinical trials](#)

Collection

- [MHRA guidance on coronavirus \(COVID-19\)](#)

# COVID trial applications



The screenshot shows the GOV.UK website with a search bar and navigation links. The main content area is titled 'Clinical trials applications for Coronavirus (COVID-19)' and includes a sub-header 'Guidance'. The text states: 'The MHRA is ready to prioritise and provide any assistance for clinical trials applications submitted for COVID-19'. Below this, there is a 'Contents' section with a list of links: 'COVID-19 trial related activity', 'Prioritising COVID-19 assessments', 'Submitting COVID-19 applications', 'Naming your study', and 'Participating in COVID-19 clinical trials'. A 'Related content' section is also visible, containing links to 'Managing clinical trials during Coronavirus (COVID-19)' and 'Clinical trials for medicines: apply for authorisation in the UK'.

GOV.UK

Search on GOV.UK

Departments Worldwide How government works Get involved  
Consultations Statistics News and communications

→ **Coronavirus (COVID-19)** | National lockdown: stay at home  
→ **Brexit** | Check what you need to do

Home > [Clinical trials and investigations](#)

Guidance

**Clinical trials applications for Coronavirus (COVID-19)**

The MHRA is ready to prioritise and provide any assistance for clinical trials applications submitted for COVID-19

From: [Medicines and Healthcare products Regulatory Agency](#)  
Published: 19 March 2020  
Last updated: 9 November 2020, see all updates

Contents

- [COVID-19 trial related activity](#)
- [Prioritising COVID-19 assessments](#)
- [Submitting COVID-19 applications](#)
- [Naming your study](#)
- [Participating in COVID-19 clinical trials](#)

Related content

- [Managing clinical trials during Coronavirus \(COVID-19\)](#)
- [Clinical trials for medicines: apply for authorisation in the UK](#)

The clinical trials unit have set up a specific mailbox for COVID-19 related trial activity;  
[Covid.clinicaltrials@mhra.gov.uk](mailto:Covid.clinicaltrials@mhra.gov.uk)

This must be used instead of the previously used clinical trial helpline email.

# Innovative licensing and Access Pathway



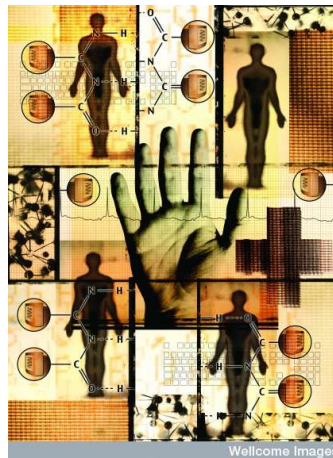
# Innovative Licensing and Access Pathway

- **Goal:** to deliver efficient and timely development of medicines and earlier patient access
- A new medicine designation links to the development of a roadmap to patient access – **Innovation Passport**
- **Target Development Profile (TDP)** creates a unique UK roadmap, utilising tools from a toolkit and providing a platform for sustained multi-stakeholder collaboration
- The regulatory toolkit is intended to drive efficiencies in the development programme, supporting data generation and evidence requirements
- An integrated pathway will pull together expertise from across the MHRA and partners in the wider healthcare system including NICE and the SMC
- Built-in flexibility, with multiple entry points along the pathway (non-clinical data → clinical trials)



# The toolkit

- Adaptive inspections
- ATMP Centre accreditation
- Novel CT methodology & design support
- Common medicine & device trial design
- Coordinated approvals process for co-developed medicines & IVDs
- CPRD assisted recruitment in clinical trials
- Rapid Clinical Trial Dossier pre-assessment service
- Certifications



- CPRD control groups
- Enhanced patient engagement
- Continuous benefit-risk assessments that integrate real word evidence
- New licensing procedures:
  - Rolling review
  - Accelerated timetables for marketing authorisation, flexibilities
  - International options
    - FDA Orbis
    - ACCESS

# Novel methodology tool

The screenshot shows the MHRA Novel Trials Workshop event page. The header features the MHRA logo and the event title 'Novel Trials Workshop'. Below the title, it specifies the dates 'Monday 12 - Tuesday 13 October 2020', the time '13:00-16:30', and the format 'Webinar'. The page is dated 'OCT 12'. The event is organized by 'Medicines and Healthcare products Regulatory Agency' and is marked as 'Free'. A green 'Register' button is prominently displayed. The main content area includes a heart icon, a section titled 'Novel Trials Workshop - 2 half day webinars.', and a section titled 'About this Event'. Under 'About this Event', there is a sub-section 'What is the event about?' which describes the workshop's focus on novel trial design and its relevance to the UK research community. The page also lists the 'Date And Time' as 'Mon, 12 Oct 2020, 13:00 - Tue, 13 Oct 2020, 16:30 BST' and includes a link to 'Add to Calendar'. The 'Location' is listed as 'Online Event'.

**MHRA**

## Novel Trials Workshop

Monday 12 - Tuesday 13 October 2020 • Time : 13:00-16:30 • Webinar

OCT 12

### Novel Trials Workshop

by Medicines and Healthcare products Regulatory Agency

[Follow](#)

Free

[Register](#)

Novel Trials Workshop - 2 half day webinars.

#### About this Event

##### What is the event about?

Novel trial design has been highlighted as a priority for the government and the wider UK research community in the Life Sciences Sector 2 Deal.

The MHRA was specifically tasked with engaging with industry in order to be able to develop and further enable access to its advice services, as well as strengthen the UK environment for novel trials in the UK.

**Date And Time**  
Mon, 12 Oct 2020, 13:00 - Tue, 13 Oct 2020, 16:30 BST  
[Add to Calendar](#)

**Location**  
Online Event

- ▶ Scientific advice support from MHRA, HTA bodies and others
- ▶ Guidance
- ▶ Events – workshops etc

# Its more than just novel trial design...



- ▶ Provide regulatory assurance on the requirements and acceptability of virtual, artificial intelligence (AI) and decentralised elements in trial conduct.
- ▶ Provide regulatory assurance on new eSystems technologies that may be used to support any such novel trial designs.

# Pre-assessment service



MHRA will offer a service for sponsors of designated clinical trials to assist with finalisation of their key documentation (protocol, IB, IMPD) for application for a Clinical Trial Authorisation (CTA).



CTU assessment team will provide feedback on documentation in an expedited timeframe to facilitate document finalisation and internal sign offs prior to the project entering the critical path. This will greatly improve the chance of the application receiving a CTA without additional requests for further information at the time of the formal submission.

# Enhanced patient engagement

## MHRA launches consultation on how to best engage patients and the public

The Medicines and Healthcare products Regulatory Agency (MHRA) has today launched a 12-week consultation on how to best engage and involve patients in the Agency's work.

Published 15 July 2019

From: [Medicines and Healthcare products Regulatory Agency](#)



The responses will help inform the MHRA's future engagement with patients and the public.

The MHRA wants to adopt a more systematic approach to listening to and involving patients. They want to make sure that the patient voice is more clearly heard when safety issues, concerning medicines or medical devices, are identified and in the licensing of new medicines.

- Enable patients to add their perspective on benefits and risks of medicines, relevance of efficacy endpoints e.g. through contribution to guidance, specific product interactions
- Wider ambition which recognises patients as partners, transforming our activity, culture and reputation in the minds of patient groups

# Combined Ways of Working (CWOW)

## ~~Combined Ways of Working (CWOW)~~



# ~~Combined Ways of Working (CWOW)~~

## Combined Review Service

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/>

### Webinars for CTIMP applicants, sponsors and NHS/HSC organisations

To help you prepare for the transition to combined review, we're running a series of free, live webinars during December. They are designed for different user groups involved in CTIMPs and will provide an overview of upcoming changes and how they may impact you, depending on your role.

You can see dates available and reserve your place using our [online booking system](#). You will need to register for an account on the [Learning Management System](#).



The combined review service, formerly called Combined Ways of Working (CWoW) will become the way all new CTIMP applications are made from 1 January 2022.

It offers CTIMP applicants and sponsors a single application route and co-ordinated review leading to a single UK decision.

## Other updates

You can formally request an extension if you need more time to respond to an RFI following the initial assessment of a CTIMP application.

Email [clintrialhelpline@mhra.gov.uk](mailto:clintrialhelpline@mhra.gov.uk) to make a request, and state how much time beyond the usual 14 days is needed. Applicants receive a final decision on their application within 10 days of receipt of a response to an RFI. Extensions can be requested to cover the Christmas period.

The HRA and ISRCTN recently announced a partnership to automatically register new clinical trials following REC favourable opinion. This will improve the visibility of UK-based research and make it easier for researchers and sponsors to fulfil their transparency responsibilities.

Free, automatic registration will start with new CTIMPs using combined review in January 2022.

CTR update

<https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-regulation>



- Clinical Trials Information System (CTIS) will go live on 31<sup>st</sup> January 2022
- There is a 3 year transition period – EudraCT will not be used for new CTA applications after January 2023
- There is extensive training and support online, as well as a modular training programme and many Q&A documents for each element of a new CTA and maintaining a CTA

- The CTR will not take effect in Northern Ireland – this remains under the remit of MHRA as part of 'UK' regulation
- Aware the addition of patient 'rights' in the serious breach definition may have caused some concern. EMA had a draft guideline in 2017 but this does not provide a specific example.
- Sponsors will need to consider updating their SOPs to account for the new CTR as well as UK legislation if conducting multinational trials.
- Any questions for MHRA – please direct to the CT Helpline:  
[clintrialhelpline@mhra.gov.uk](mailto:clintrialhelpline@mhra.gov.uk)

# Legislation updates

# UK CT Legislation updates

- Keep a lookout in January for the consultation
- Seeks opinion on changes such as Patient and Public Involvement, transparency and processes for the actual applications
- Some areas are to align with the CTR and some areas will deliberately remain mis-aligned



# Questions?



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