MHRA Update, December 2021

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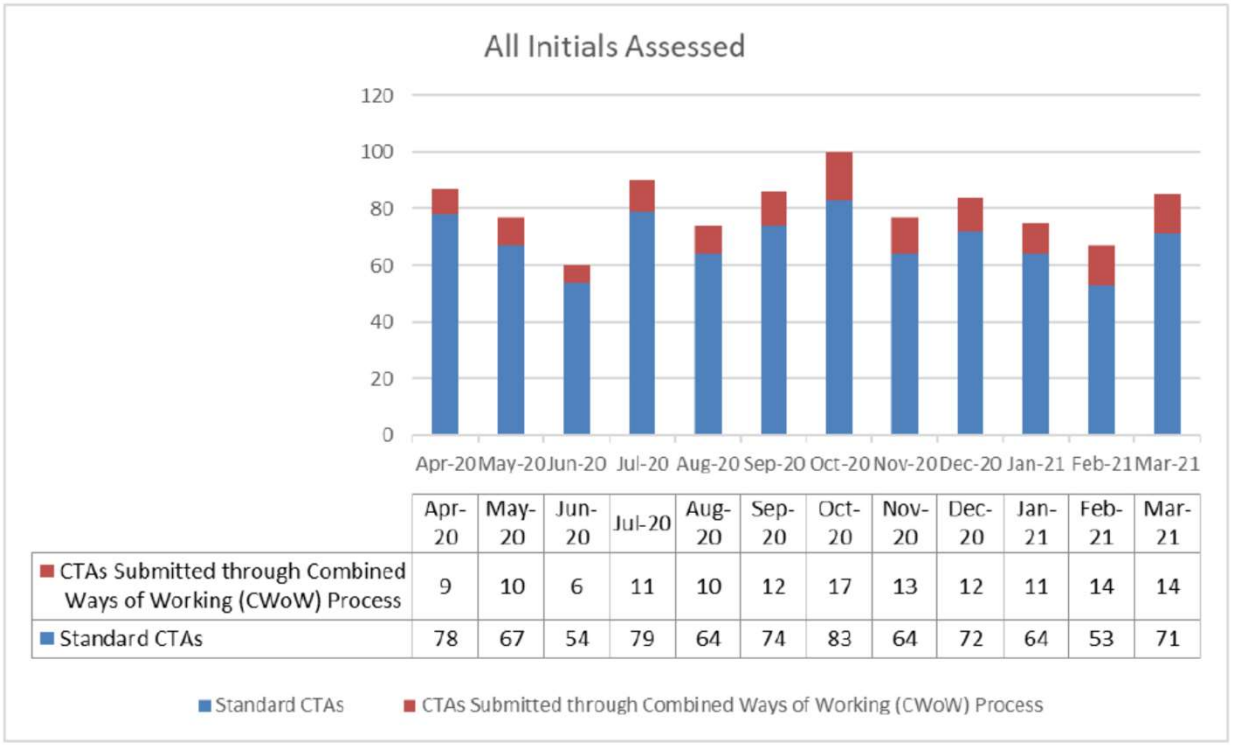
Medicines & Healthcare products Regulatory Agency

Agenda

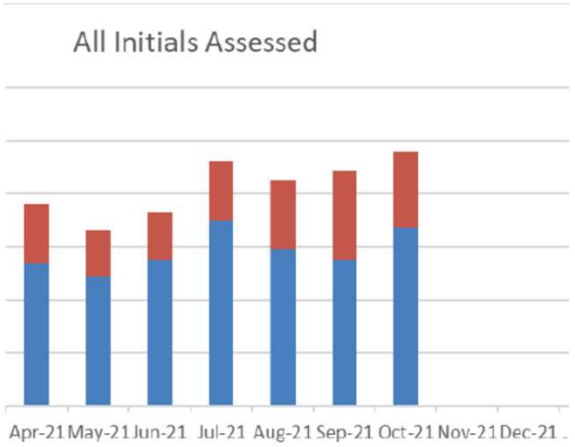
- Metrics
- Novel trials and COVID
- Brief ILAP update
- Combined review from January 2022
- CTR and impact in UK
- Legislation update

Metrics

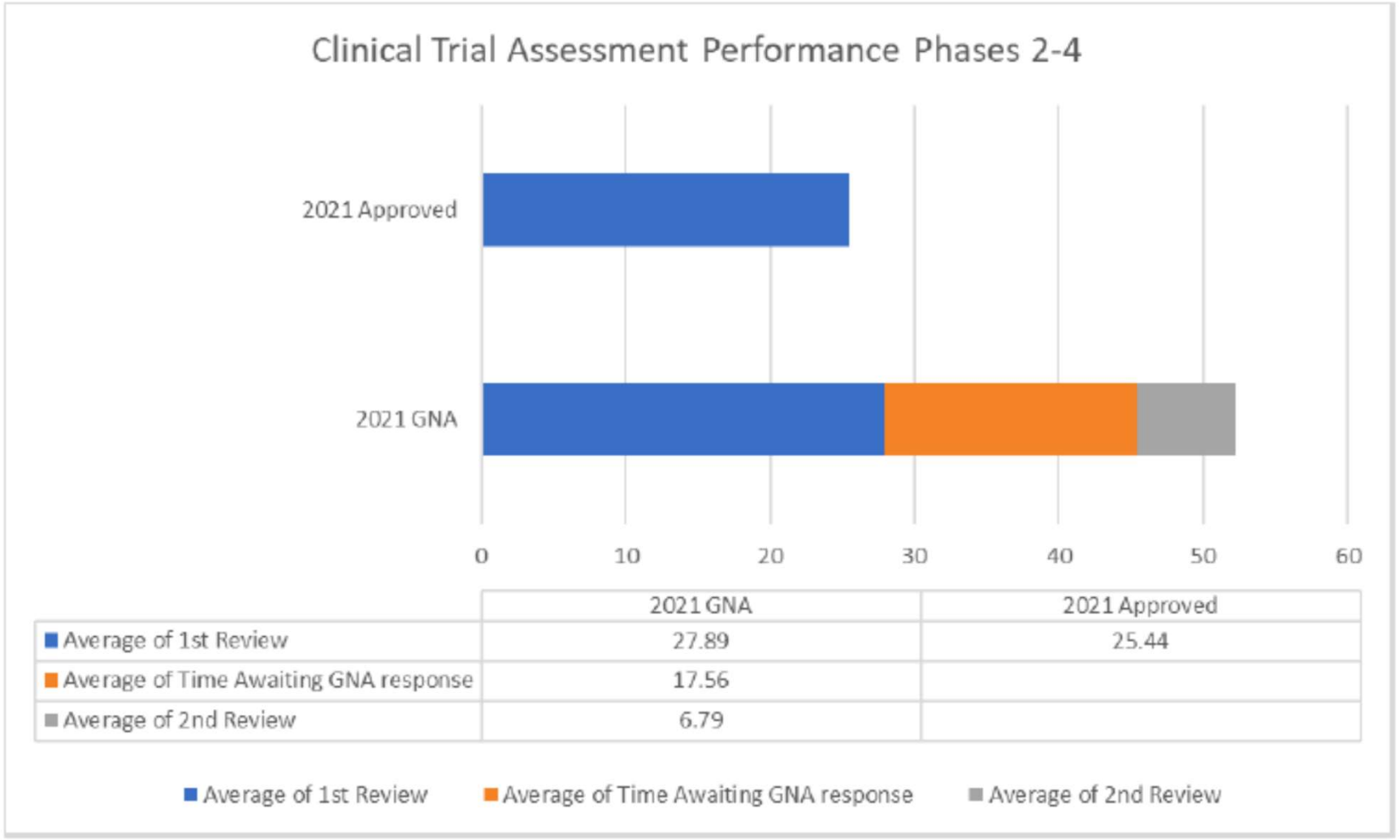
https://www.gov.uk/government/publications/clinical-trials-for-medicines-authorisation-assessment-performance



	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



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		

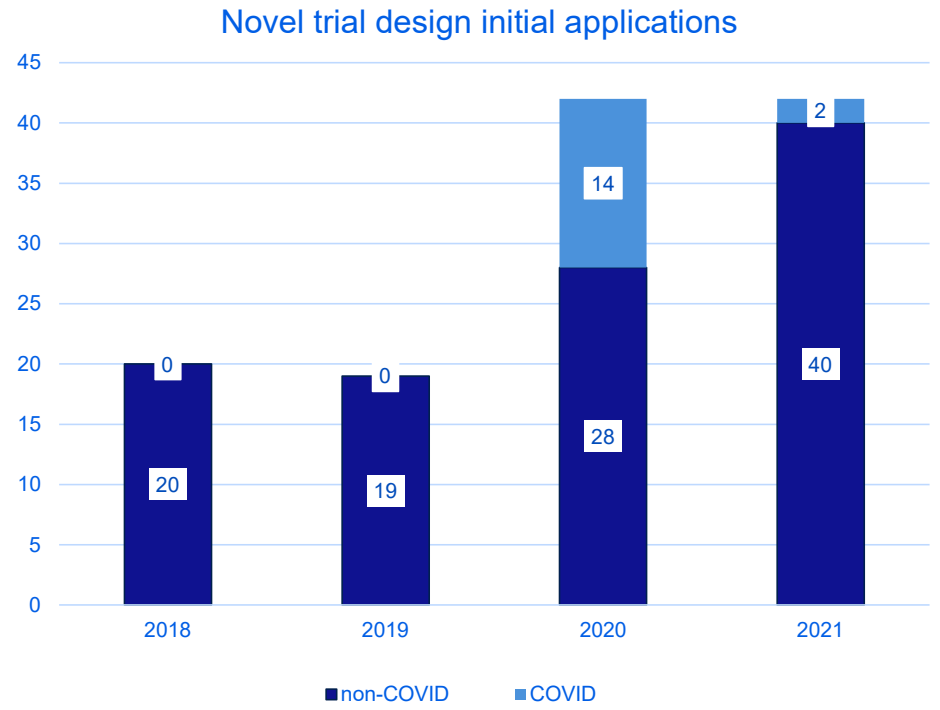


	2021 GNA	2021 Approved
Average of 1st Review	27.89	25.44
Average of Time Awaiting GNA response	17.56	
Average of 2nd Review	6.79	

Metrics – novel trial designs, inc. COVID-19

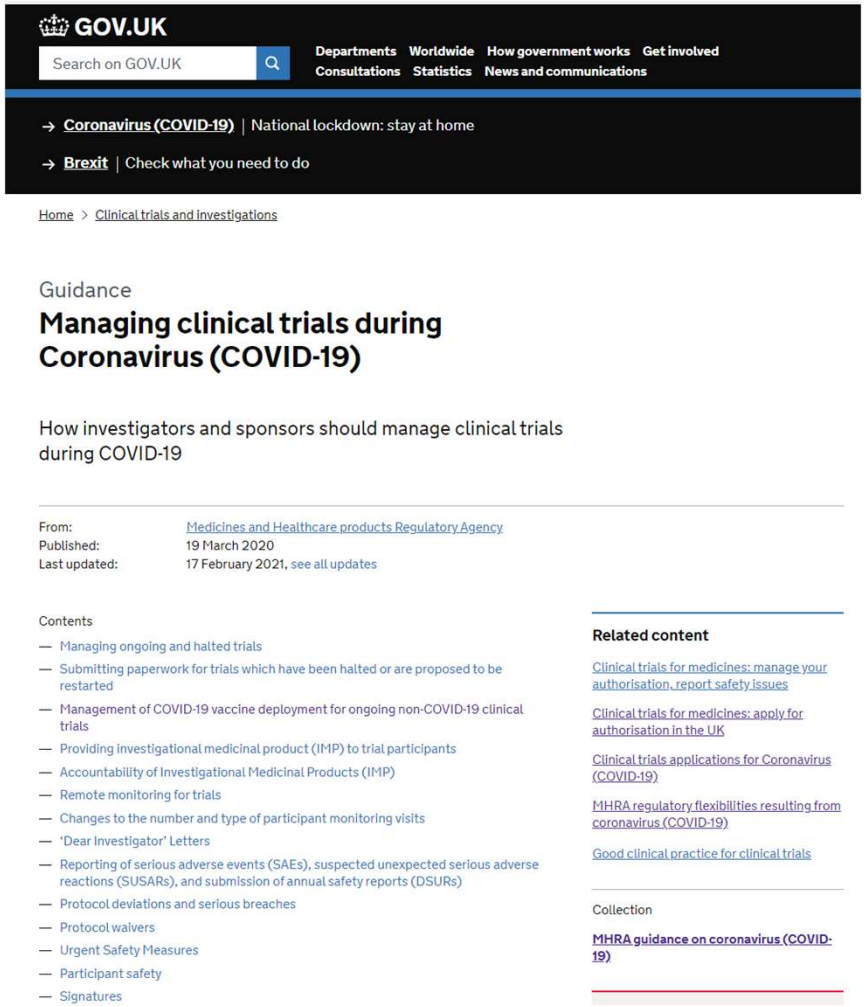
- MHRA CTU has been tracking these trials since January 2018.

- COVID-19 saw a rise in submissions – supported by NIHR and Chief Medical Officer
- Recovery
- Principle
- REMAP-CAP
- Others…..

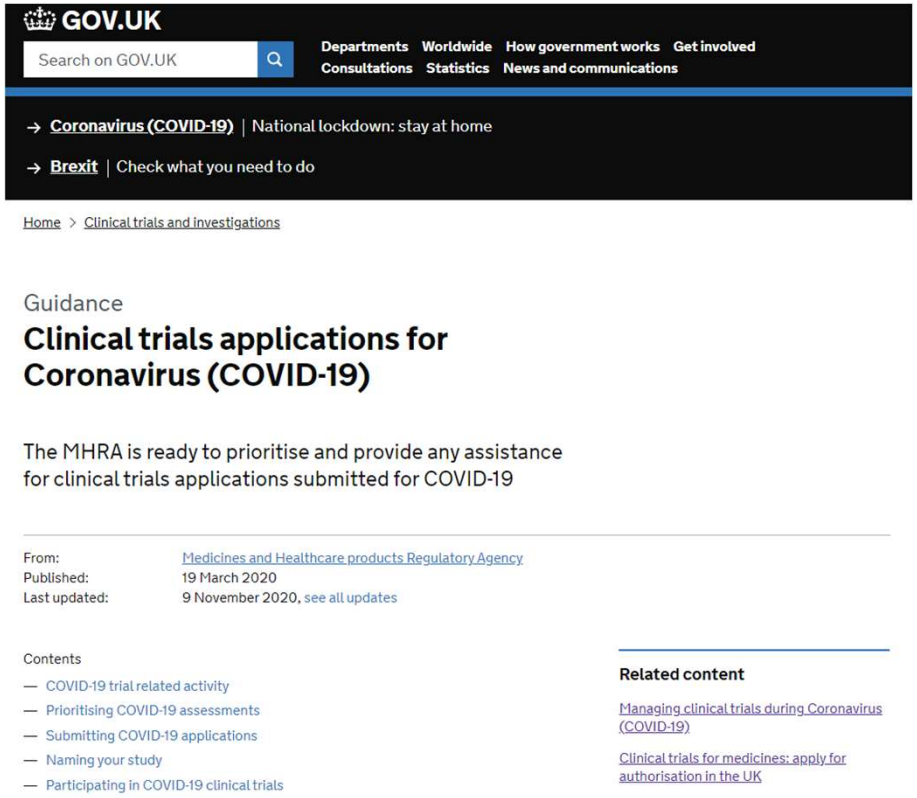


Lots of information…

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



COVID trial applications


GOV.UK

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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

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

Innovative licensing and Access Pathway

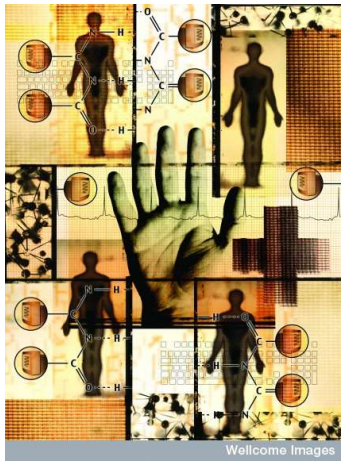
Innovative Licensing and Access Pathway

- **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 mutli-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)

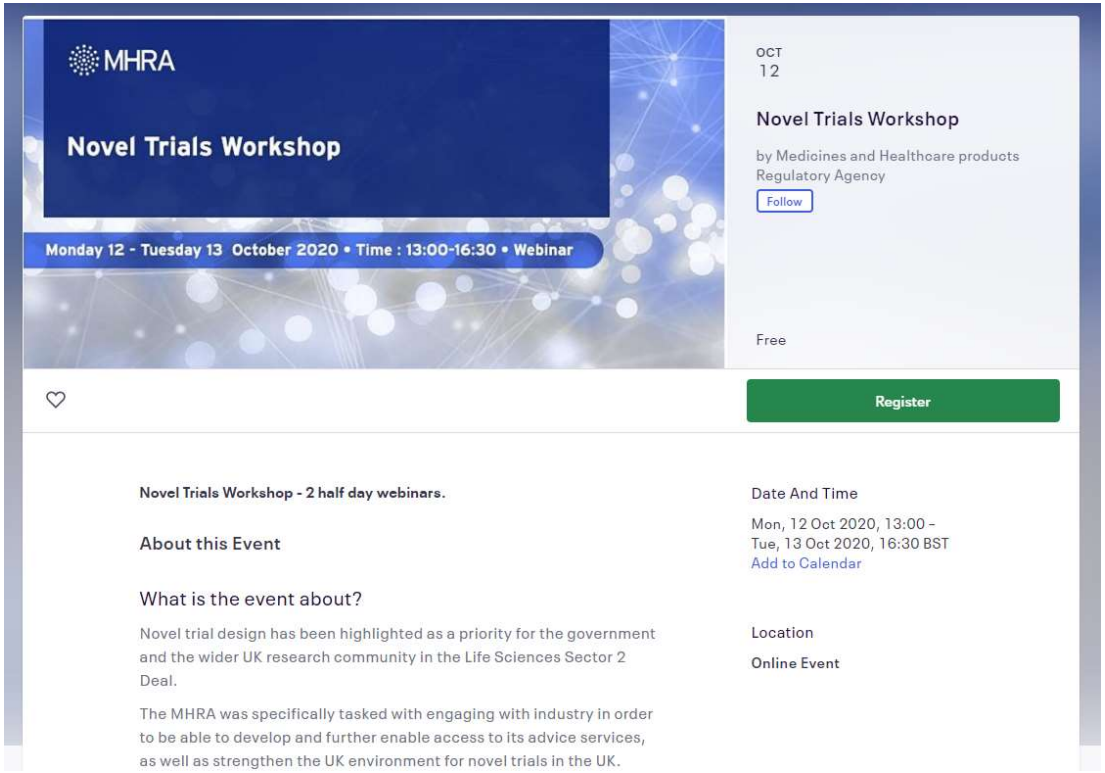
The toolkit

- 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



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

Its more than just novel trial design…

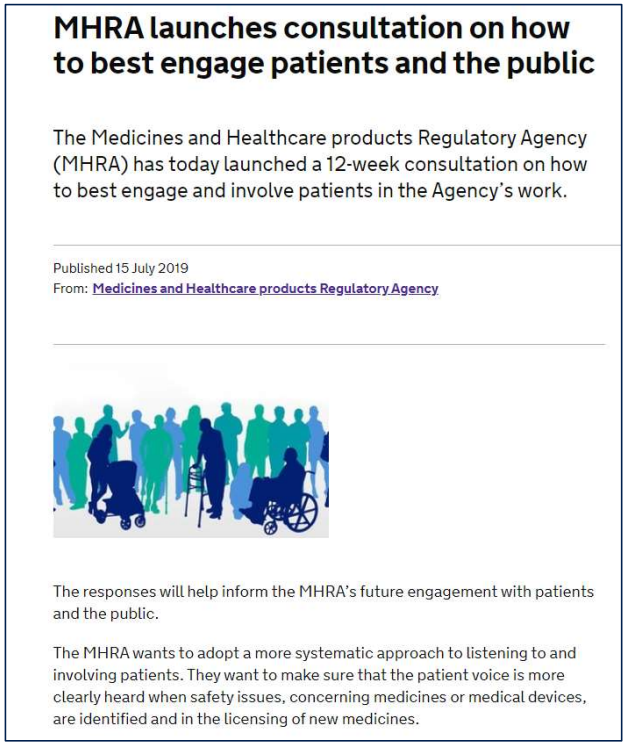
- Provide regulatory assurance on the requirements and acceptability of virtual, artificial intelligence (AI) and decentralised elements in trial conduct.
- Provide regulatory assurance on new eSystems technologies that may be used to support any such novel trial designs.

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

- 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)

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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 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 31st 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

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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