Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Changes / updates to clinical trial legislation and approvals

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

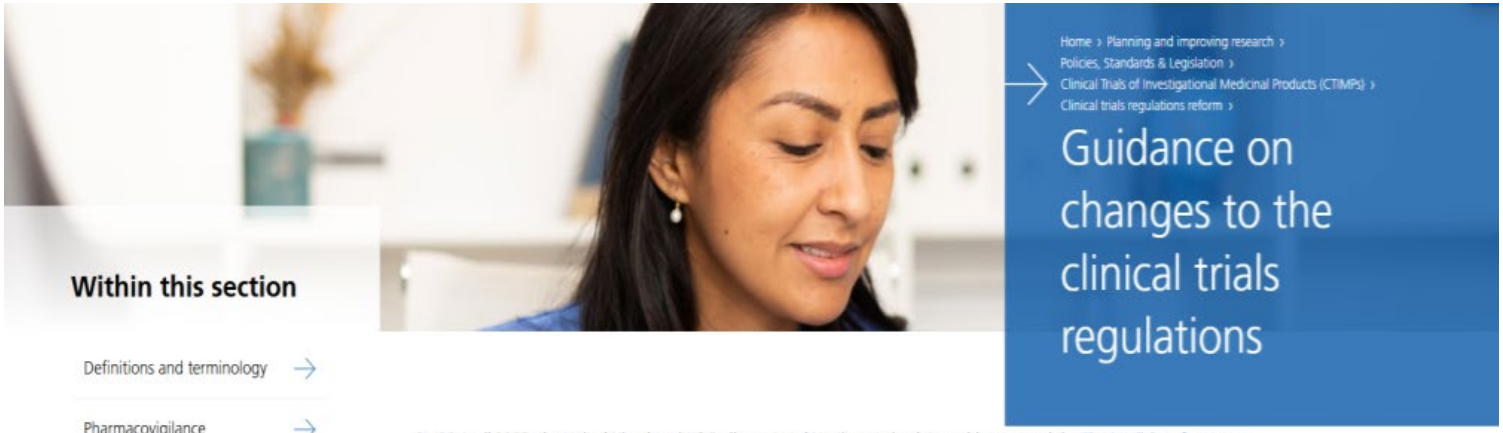
Health Research Authority (HRA)

NHS
Health Research Authority

[Guidance on changes to the clinical trials regulations - Health Research Authority]

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Guidance on changes to the clinical trials regulations



Home › Planning and improving research › Policies, Standards & Legislation › Clinical Trials of Investigational Medicinal Products (CTIMPs) › Clinical trials regulations reform ›

Guidance on changes to the clinical trials regulations

Within this section

- Definitions and terminology
- Pharmacovigilance
- The approvals process for clinical trials
- Simplified arrangements for consent in clinical trials
- Research Ethics Committees that review clinical trials
- Research transparency requirements for clinical trials

On 28 April 2025, the United Kingdom (UK) Parliament and Northern Ireland Assembly approved the The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

These new regulations introduce changes to the Medicines for Human Use (Clinical Trials) Regulations 2004 which currently govern the regulation of clinical trials involving investigational medicinal products (CTIMPs) in the UK.

The changes to the regulations are based on feedback from a public consultation in 2023, which included input from various stakeholders on beneficial changes to the existing legislation.

While Parliament has approved the updates, the new regulations will not come into force until 28 April 2026. This means that CTIMPs will continue to follow the Medicines for Human Use (Clinical Trials) Regulations 2004 until 27 April 2026.

The existing guidance on the HRA website will give you up to date information on how you should submit, manage and conduct CTIMPs in compliance with the 2004 regulations.

When the new regulations do come into force, they will apply across all four nations of the UK (England, Wales, Scotland and Northern Ireland). All clinical trials taking place in the UK will be required to comply with the updated regulations.

To help you understand and prepare for the new requirements, we have developed guidance that outlines the changes:

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

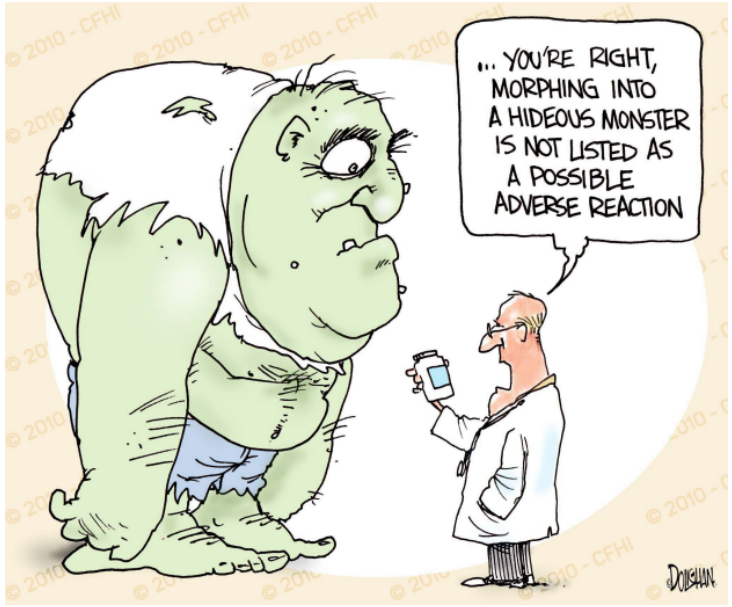
New definitions

- Non-investigational medicinal product
- Notifiable trial
- Public registry

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Pharmacovigilance

- Suspected unexpected serious adverse reactions (SUSARs) and annual safety reports
- Urgent safety measures (USMs)

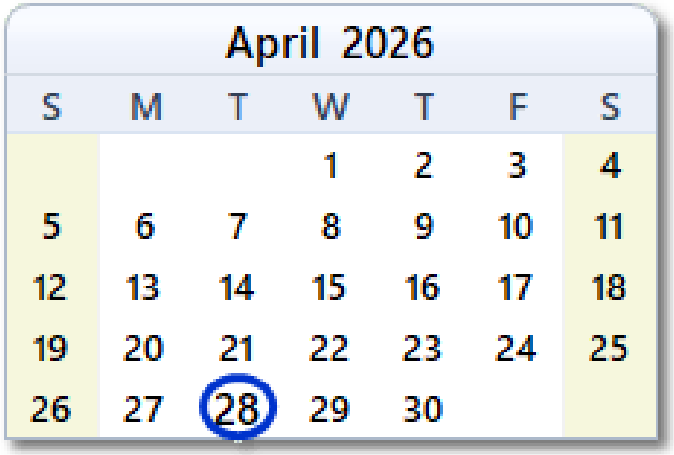


Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

The approvals process for clinical trials

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Submission of applications



Tuesday, Apr 28th 2026

Medicines & Healthcare products Regulatory Agency

NHS
Health Research Authority

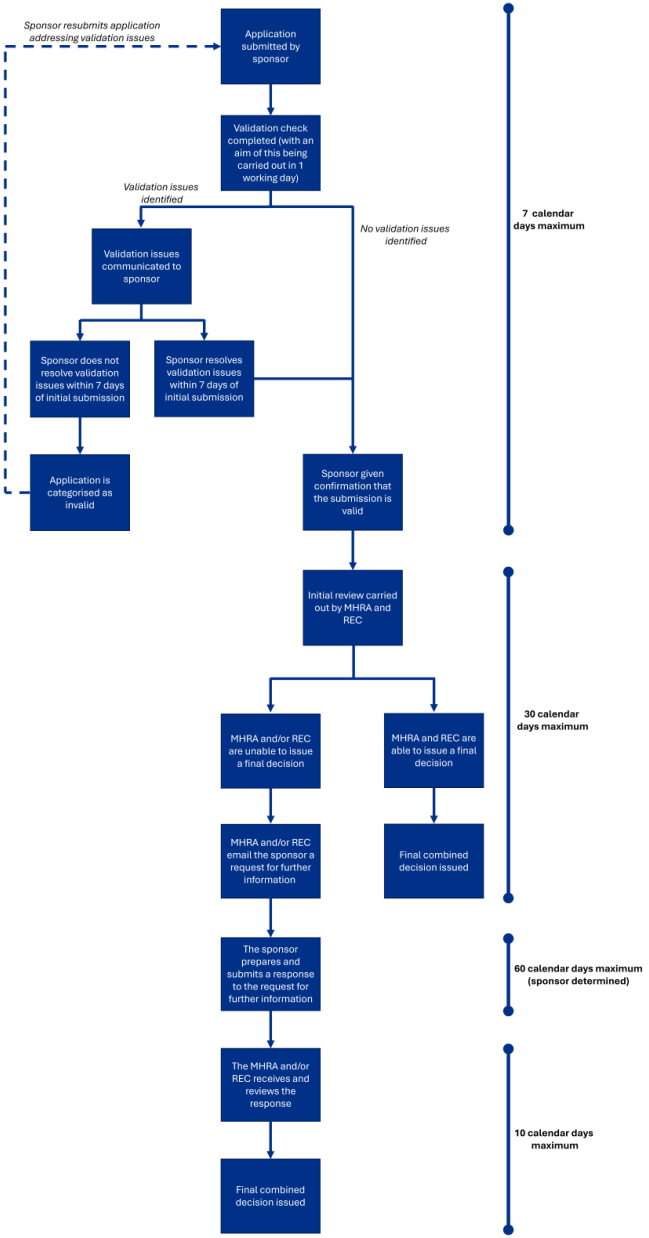
Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

The approvals process for applications

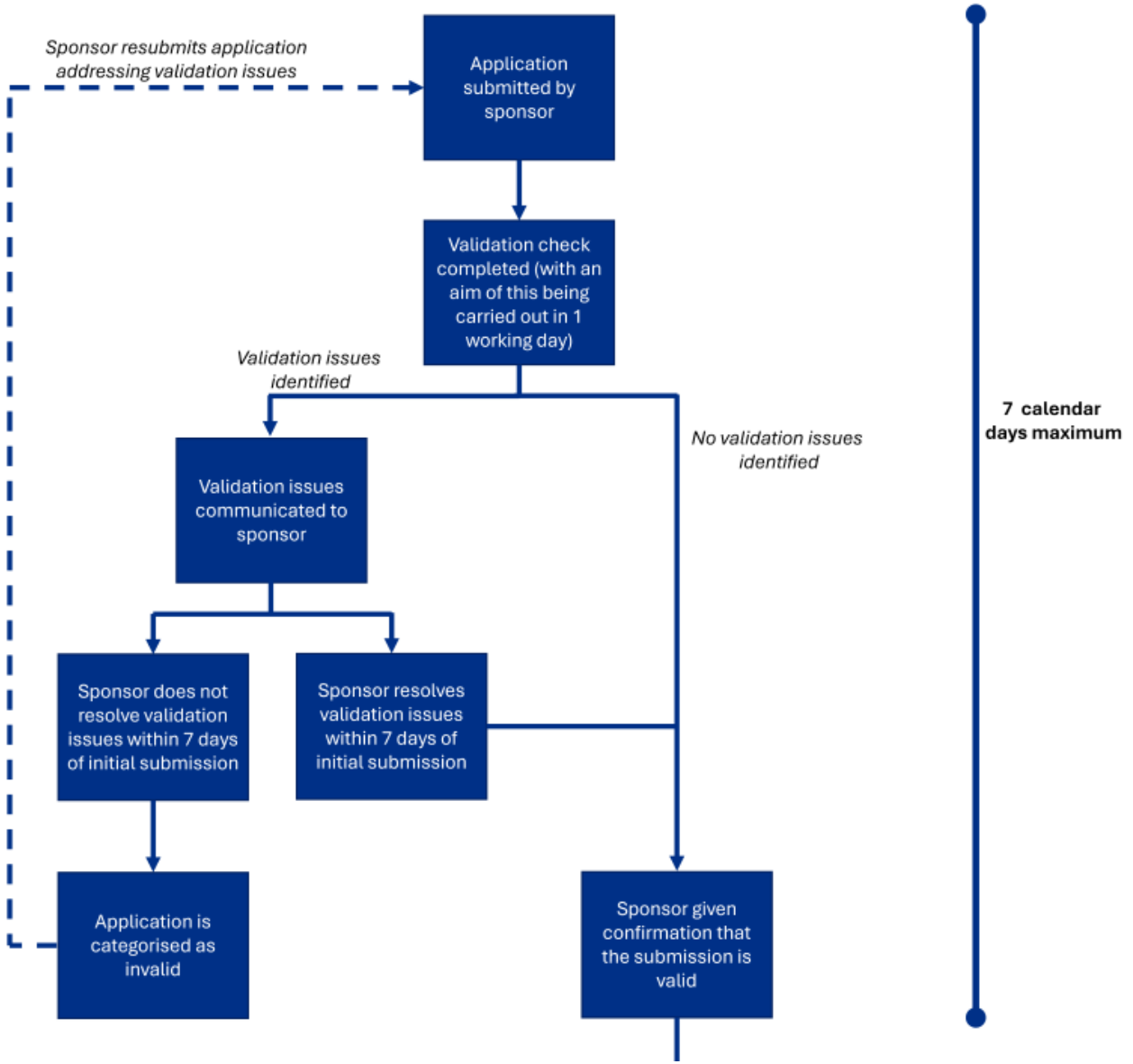
Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

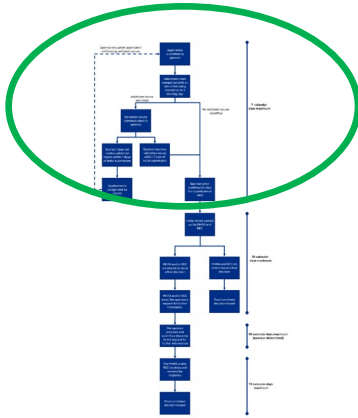
Initial application timeframes and process



Ymchwil Iechyd a Gofal Cymru
Health and Care Res

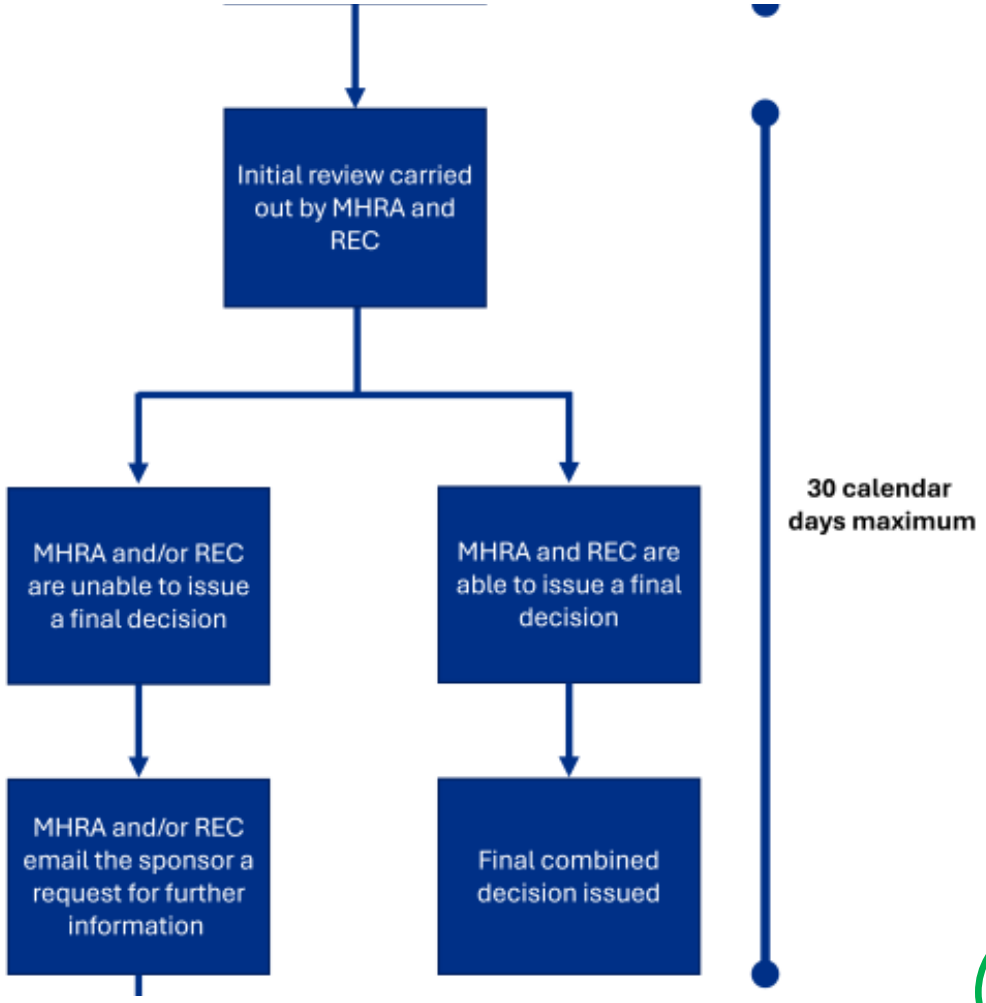
Initial application timeframes and process

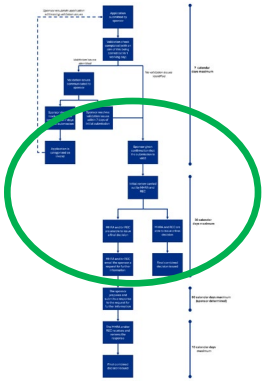




Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Initial application timeframes and process





Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Initial review outcomes

- favourable opinion
- favourable opinion subject to conditions
- unable to issue an opinion

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Initial application timeframes and process

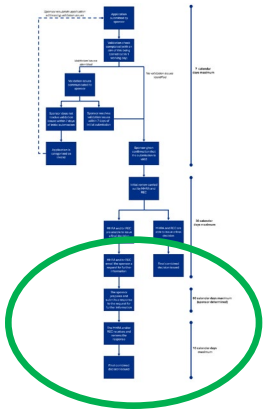
The sponsor prepares and submits a response to the request for further information

60 calendar days maximum (sponsor determined)

The MHRA and/or REC receives and reviews the response

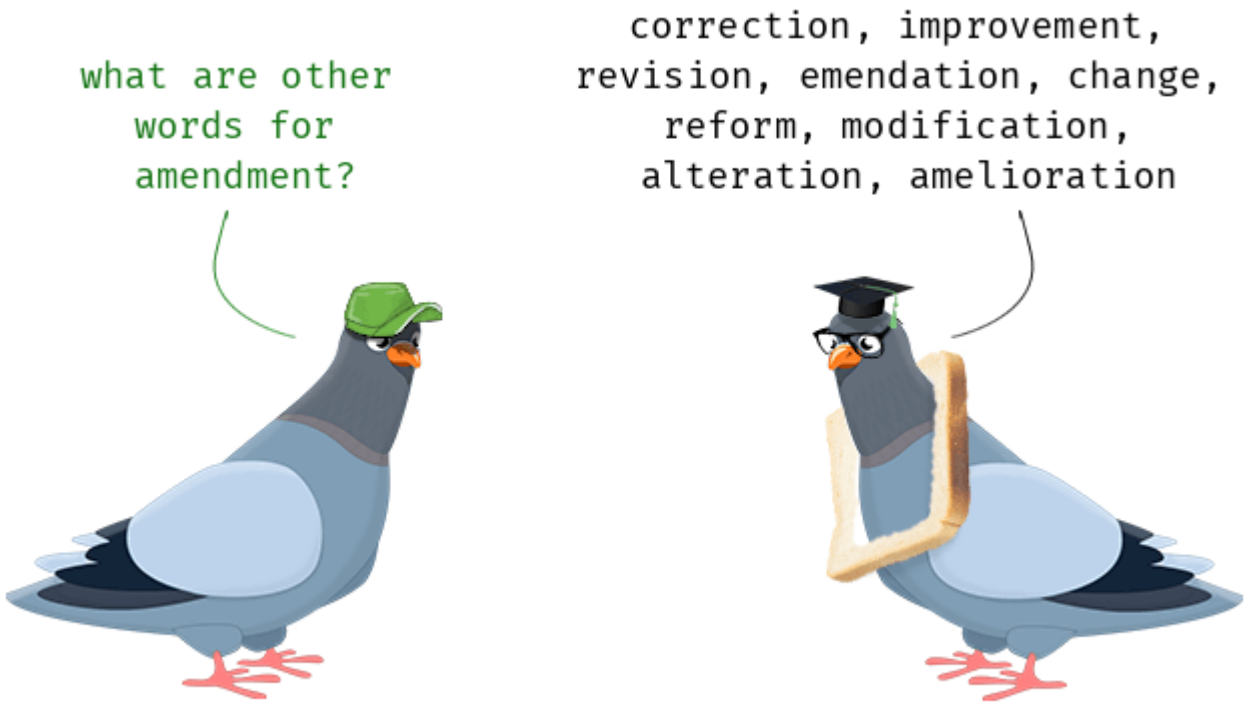
10 calendar days maximum

Final combined decision issued



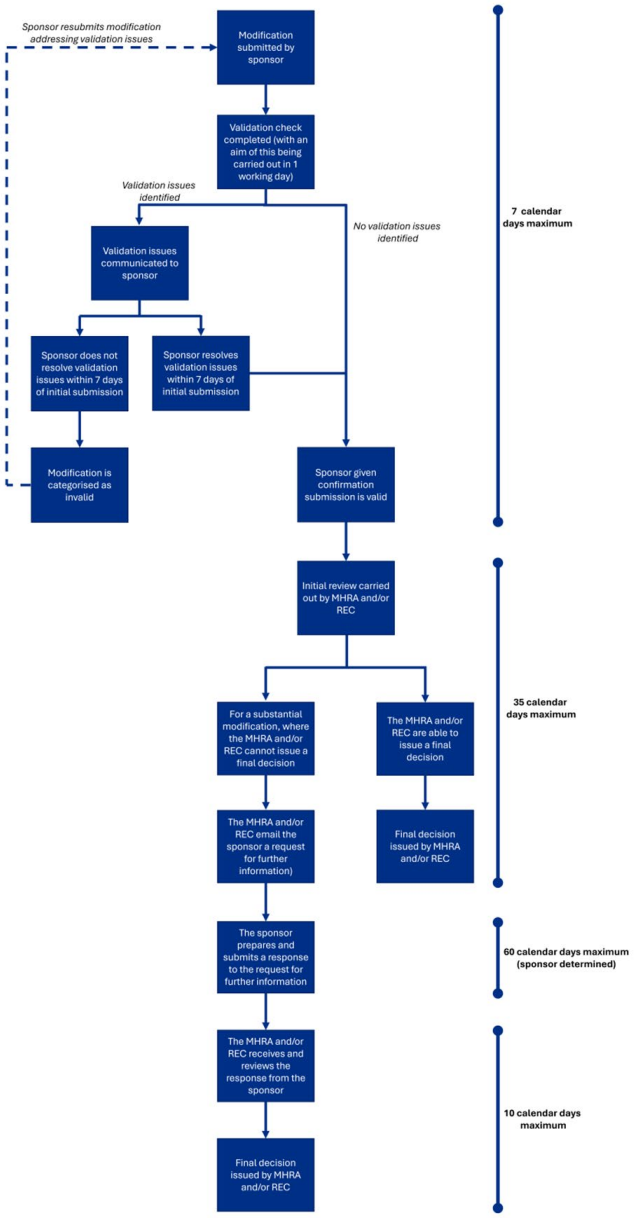
Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

The approvals process for modifications (formerly known as amendments)



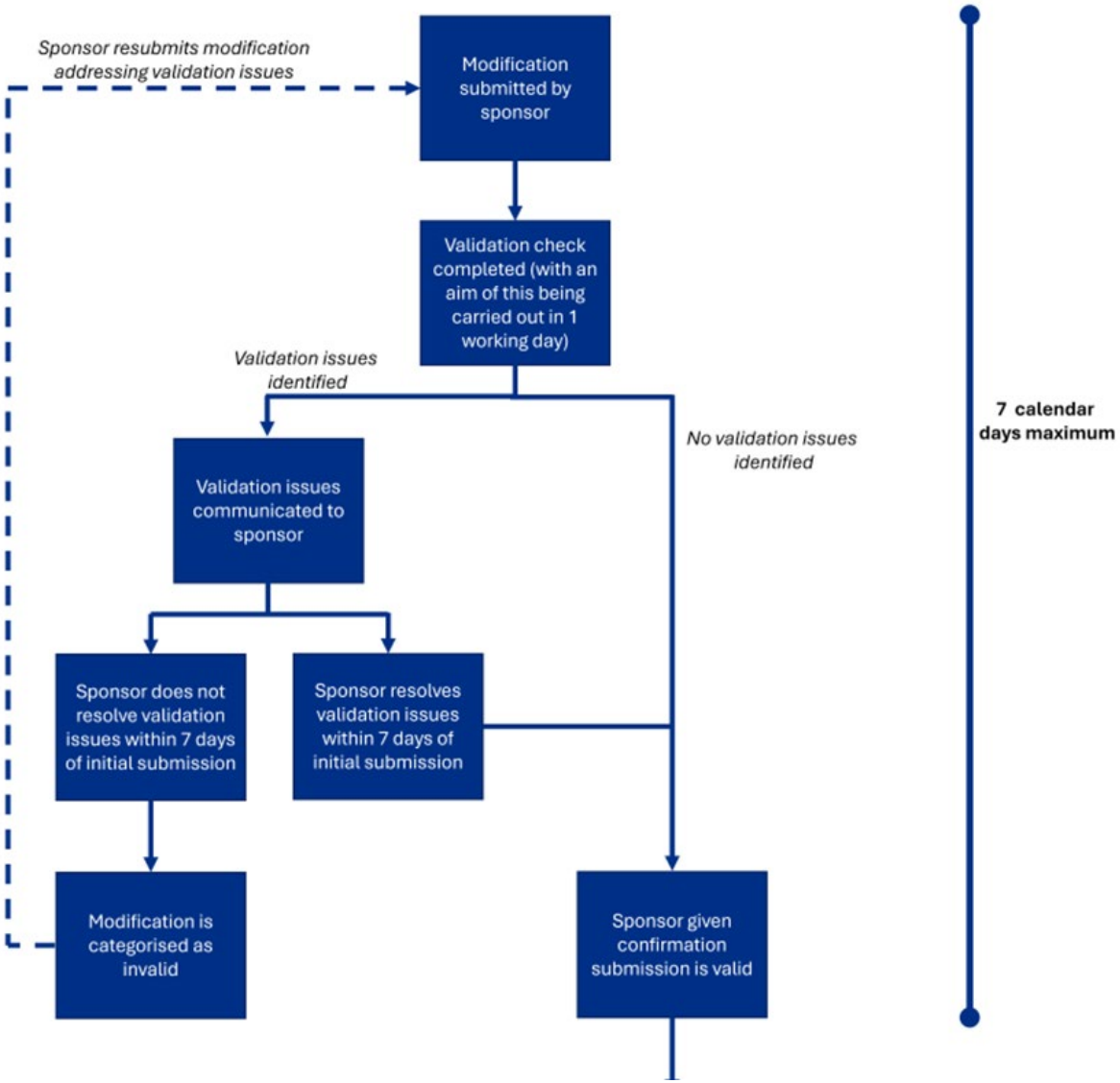
Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

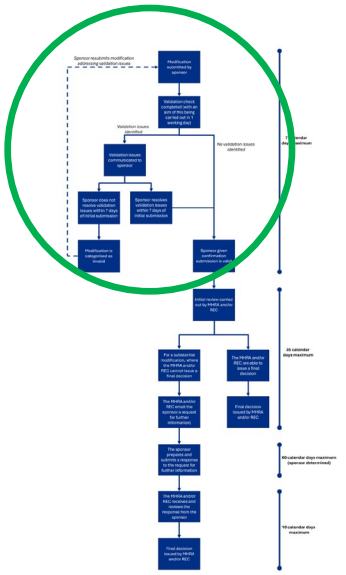
Modification timeframe and process



Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

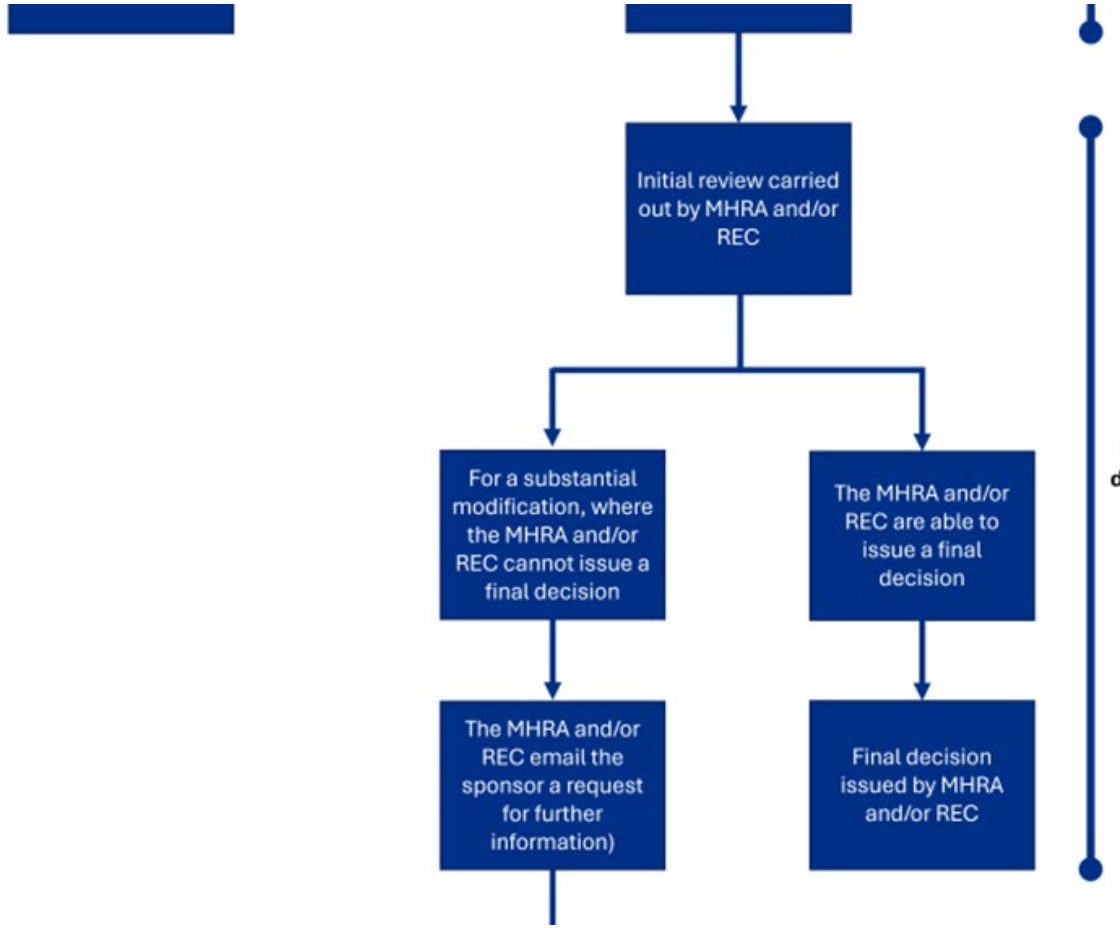
Modification timeframe and process

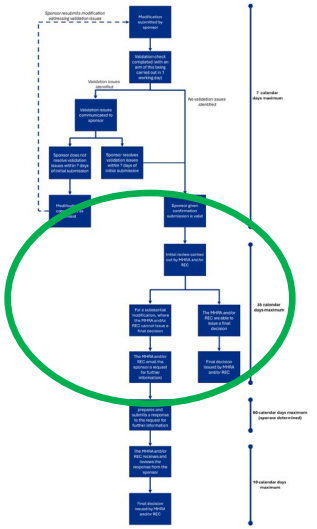




Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Modification timeframe and process





Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Modification timeframe and process

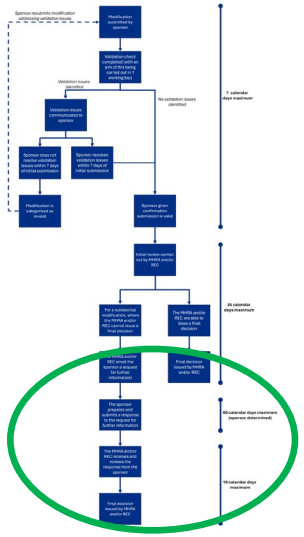
The sponsor prepares and submits a response to the request for further information

The MHRA and/or REC receives and reviews the response from the sponsor

Final decision issued by MHRA and/or REC

60 calendar days maximum (sponsor determined)

10 calendar days maximum



Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

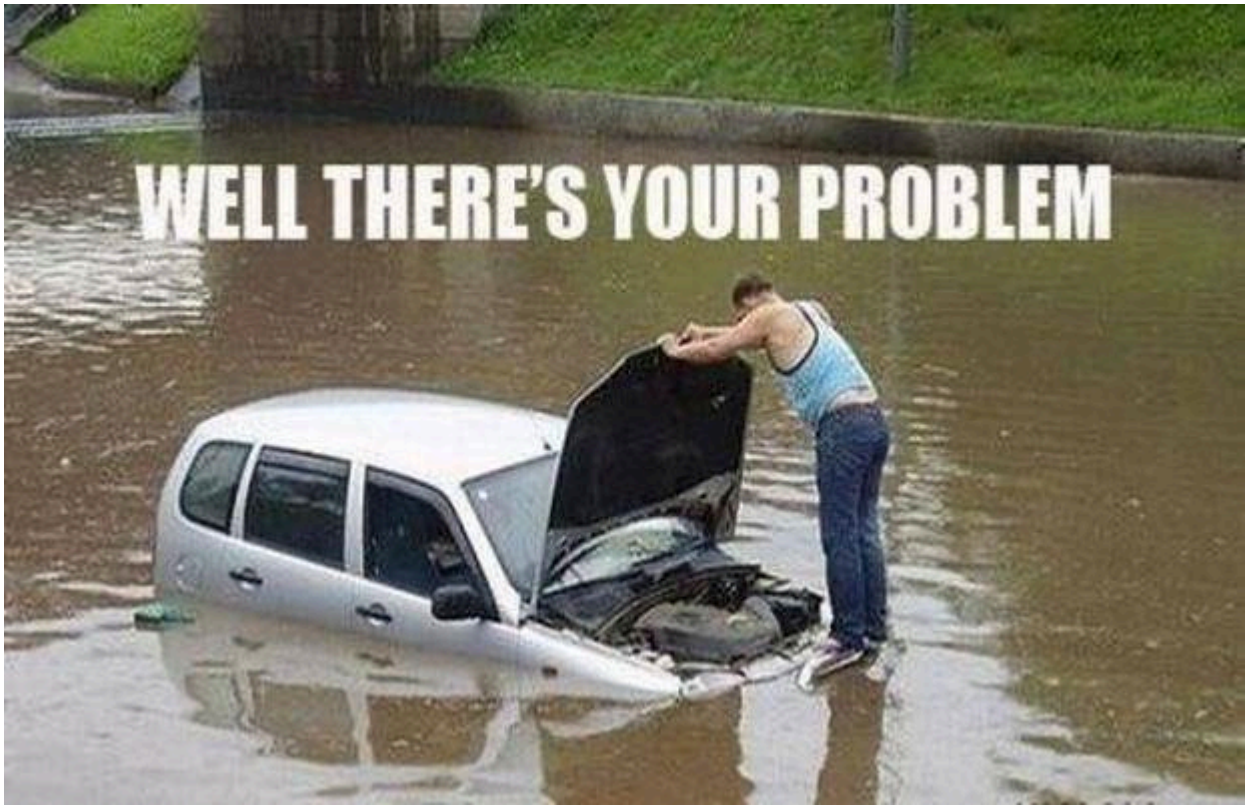
MHRA and REC reviewing a response to a request for further information

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

MHRA and REC requesting modifications post-approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

When can the REC or MHRA request a modification?



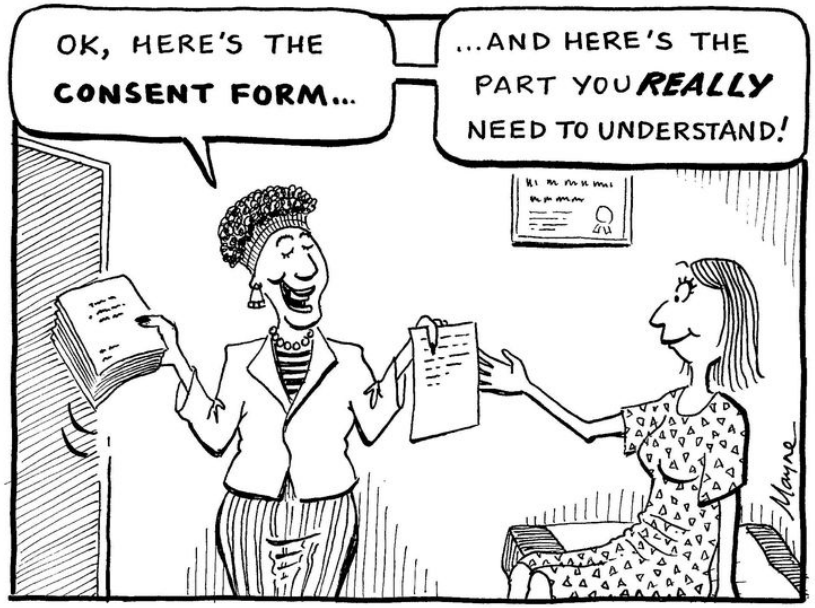
Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Approval lapsing for trials with no recruitment

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Simplified arrangements for consent in clinical trials

- **What 'simplified arrangements' may be used?**



Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Research Ethics Committees that review clinical trials

- Constitution of RECs
- Attendance requirements for full meetings of the REC

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Research transparency requirements for clinical trials

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

New IRAS

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

References

- Guidance on changes to the clinical trials regulations - Health Research Authority

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Contact

- Email:

Gurmel.Bhachu@wales.nhs.uk

- LinkedIn:

Gurmel Bhachu