

# Modification Tool

v2.1 24 April 2026

For office use

QC: No

## Section 1: Project information

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |       |          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|
| Short project title*:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | PANTHER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |       |          |
| IRAS project ID* (or REC reference if no IRAS project ID is available):                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 1008743                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |       |          |
| Sponsor modification reference number*:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Substantial Modification 2 (SM02)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |       |          |
| Sponsor modification date* (enter as DD/MM/YY):                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 22 July 2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |       |          |
| Briefly summarise in lay language the main changes proposed in this modification. Explain the purpose of the changes and their significance for the project. If the modification significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*: | <p>1. Master protocol updates</p> <ul style="list-style-type: none"> <li>-Clarification of blood gas parameters in the eligibility assessment of ARDS</li> <li>-Clarifications around safety outcome reporting (within 28 days in line with SAEs)</li> <li>- Addition of New-Onset Atrial Fibrillation (NOAF) as a safety outcome</li> <li>- ECMO added as primary endpoint</li> <li>- Addition of ventilator support as a secondary endpoint</li> <li>- Clarification that patients will receive usual care or usual care + intervention</li> <li>- Update to protocol to confirm medians for reporting</li> <li>- The addition of the Brief Health Literacy Screening Tool, Labour market outcomes- including return to work, time off work and reason for time off work, as tertiary outcome</li> </ul> <p>2. Update to original application to reflect that PANTHER Is running in the US, Japan, EEA, Canada &amp; Australia</p> <p>3. Request to extend labelling exemption originally granted for the study under the new Clinical Trial Regulations.</p> <p>4. Correction, the impact assessment scale (6pt scale) is being submitted in replacement of the previously submitted 22 point scale.</p> <ul style="list-style-type: none"> <li>-Addition of the IQCODE questionnaire</li> <li>- Addition of the Brief Health Literacy Screening Tool</li> </ul> <p>5. Update to UK Region Specific Appendix (RSA) to change the approval of the UK RSA (and all subsequent country RSAs) from the ITMG to the Executive Committee.</p> <p>6. Updated SmPCs submitted</p> |       |          |
| Project type (select):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <div>Specific project</div> <div>Research tissue bank</div> <div>Research database</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |       |          |
| Has the project been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this modification?:                                                                                                                                                                                                                                                                                                                                                                                                          | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No    |          |
| What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):                                                                                                                                                                                                                                                                                                                                                                                                                             | <div>NHS/HSC REC</div> <div>Ministry of Defence (MoDREC)</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       |          |
| Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the project based?:                                                                                                                                                                                                                                                                                                                                                                                                                                    | England                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Wales | Scotland |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No    | No       |
| Was the project a clinical trial of an investigational medicinal product (CTIMP) OR does the modification make it one?:                                                                                                                                                                                                                                                                                                                                                                                                   | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No    |          |
| EudraCT number* (if the project has a EudraCT number enter it here. If the project does not have a EudraCT number enter "N/A"):                                                                                                                                                                                                                                                                                                                                                                                           | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |       |          |
| Was this clinical trial of an investigational medicinal product (CTIMP) processed under the CTIMP combined review service (formerly known as the Combined Ways of Working (CWoW) pilot)?:                                                                                                                                                                                                                                                                                                                                 | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No    |          |
| Did the project receive Pharmacy Assurance?:                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No    |          |
| Was the project a clinical investigation or other study of a medical device OR does the modification make it one?:                                                                                                                                                                                                                                                                                                                                                                                                        | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | No    |          |

|                                                                                                                                                                                                                                                                                                                      |         |       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------|
| Was the project a performance evaluation study of an In Vitro Diagnostic (IVD) medical device <sup>^</sup> (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:                                                                                                       | Yes     | No    |
| Does the modification make the project a performance evaluation study of an In Vitro Diagnostic (IVD) medical device <sup>^</sup> (including as a companion diagnostic in a clinical trial of an investigational medicinal product)?:                                                                                | Yes     | No    |
| <sup>^</sup> IVD medical devices are tests used on biological samples, such as tissues, blood or urine, to determine the status of a person's health. This may be a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination    |         |       |
| Did the project involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the modification introduce this?:                                                                                                                                                                    | Yes     | No    |
| Did the project involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the modification introduce this?:                                                                                                                                   | Yes     | No    |
| Did the project involve adults lacking capacity OR does the modification introduce this?:                                                                                                                                                                                                                            | Yes     | No    |
| Does the project involve access to confidential patient information outside the direct care team without consent OR does the modification introduce this?:<br>(e.g. the project relies upon section 251 support in England and Wales, or equivalent in Scotland to set aside the common law duty of confidentiality) | Yes     | No    |
| Does the project involve prisoners or young offenders who are in custody or supervised by the probation service OR does the modification introduce this?:                                                                                                                                                            | Yes     | No    |
| Does the project involve children OR does the modification introduce this?:                                                                                                                                                                                                                                          | Yes     | No    |
| Did the study involve NHS/HSC organisations prior to this modification?:                                                                                                                                                                                                                                             | Yes     | No    |
| Did the study involve non-NHS/HSC organisations OR does the modification introduce them?:                                                                                                                                                                                                                            | Yes     | No    |
|                                                                                                                                                                                                                                                                                                                      | England | Wales |
| Lead nation for the study:                                                                                                                                                                                                                                                                                           | Yes     | No    |
| Which nations had participating NHS/HSC organisations prior to this modification?                                                                                                                                                                                                                                    | Yes     | No    |
| Which nations will have participating NHS/HSC organisations after this modification?                                                                                                                                                                                                                                 | Yes     | No    |

Section 2: Summary of change(s)

What do you want to update?:

Chief Investigator
Sponsor Group
Administrative

Project information

**Please note:** Each change being made as part of the modification must be entered separately. For example, if a modification to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the modification tool as three separate changes. A list of all possible changes is available on the "Glossary of Options" tab. To add another change, click the "Add another change" box.

| Change 1                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |       |          |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|------------------|
| Area of change (select)*:                                                                                                                                                                                 | Project documents                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |       |          |                  |
| Specific area of change (select - only available when area of change is selected first)*:                                                                                                                 | Protocol - significant changes that do affect safety or the scientific value                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |       |          |                  |
| Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered): | Clarification of blood gas parameters in the eligibility assessment of ARDS, safety outcome reporting (within 28 days in line with SAEs), addition of New-Onset Atrial Fibrillation (NOAF) as a safety outcome, ECMO added as primary endpoint, addition of ventilator support as a secondary endpoint, clarification that patients will receive usual care or usual care + intervention, update to protocol to confirm medians for reporting, The addition of the Brief Health Literacy Screening Tool, Labour market outcomes- including return to work, time off work and reason for time off work, as tertiary outcomes |       |          |                  |
| Applicability:                                                                                                                                                                                            | England                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Wales | Scotland | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                                                          | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | No    | Yes      | Yes              |
| Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):                               | All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       | Some     |                  |
| Remove all changes below                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |       |          |                  |

| Change 2                                                                                                                                                                                                  |                                                                                                             |       |          |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|-------|----------|--------------------------|
| Area of change (select)*:                                                                                                                                                                                 | Project management                                                                                          |       |          |                          |
| Specific area of change (select - only available when area of change is selected first)*:                                                                                                                 | Non-UK countries - inclusion or withdrawal of an EU Member State or third country                           |       |          |                          |
| Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered): | Update to original application to reflect that PANTHER Is running in the US, Japan, EEA, Canada & Australia |       |          |                          |
| Applicability:                                                                                                                                                                                            | England                                                                                                     | Wales | Scotland | Northern Ireland         |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                                                          | Yes                                                                                                         | No    | Yes      | Yes                      |
| Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):                                       | All                                                                                                         |       | Some     |                          |
|                                                                                                                                                                                                           |                                                                                                             |       |          | Remove all changes below |

| Change 3                                                                                                                                                                                                  |                                                                                                                                                                       |       |          |                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|--------------------------|
| Area of change (select)*:                                                                                                                                                                                 | CTIMP IMP                                                                                                                                                             |       |          |                          |
| Specific area of change (select - only available when area of change is selected first)*:                                                                                                                 | Other - please specify in the free text below                                                                                                                         |       |          |                          |
| Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered): | An exemption to labelling IMP was previously granted for the study with the original application. We would like to extend this exemption under the new CT regulations |       |          |                          |
| Applicability:                                                                                                                                                                                            | England                                                                                                                                                               | Wales | Scotland | Northern Ireland         |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                                                          | Yes                                                                                                                                                                   | No    | Yes      | Yes                      |
| Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):                                       | All                                                                                                                                                                   |       | Some     |                          |
|                                                                                                                                                                                                           |                                                                                                                                                                       |       |          | Remove all changes below |

| Change 4                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                     |       |          |                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------|--------------------------|
| Area of change (select)*:                                                                                                                                                                                                                                                                                                                             | Participant procedures                                                                                                                                                                                                                                                                                                              |       |          |                          |
| Specific area of change (select - only available when area of change is selected first)*:                                                                                                                                                                                                                                                             | Participant procedures - significant change that can be implemented within existing resource at participating organisations - please specify in the free text below                                                                                                                                                                 |       |          |                          |
| Further information: explain what the change is, why the change is being made and any possible impact on participants/carers. In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)* | <p>Correction, the impact assessment scale (6pt scale) is being submitted in replacement of the previously submitted 22 point scale - Impact of events scale 6pt v1.0 22.07.2026</p> <p>IQCode questionnaire added - PANTHER IQCODE v1.0 22.07.2026</p> <p>Addition of the Brief Health Literacy Screening Tool v1.0 10.10.2023</p> |       |          |                          |
| Applicability:                                                                                                                                                                                                                                                                                                                                        | England                                                                                                                                                                                                                                                                                                                             | Wales | Scotland | Northern Ireland         |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                                                                                                                                                                                                      | Yes                                                                                                                                                                                                                                                                                                                                 | No    | Yes      | Yes                      |
| Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):                                                                                                                                                                                   | All                                                                                                                                                                                                                                                                                                                                 |       | Some     |                          |
|                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                     |       |          | Remove all changes below |

| Change 5                                                                                  |                                                                                      |
|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Area of change (select)*:                                                                 | Project documents                                                                    |
| Specific area of change (select - only available when area of change is selected first)*: | Protocol - non-significant changes that do not affect safety or the scientific value |

|                                                                                                                                                                                                           |                                                                                                                                                              |       |                          |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|--------------------------|------------------|
| Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered): | Update to UK Region Specific Appendix (RSA) to change the approval of the UK RSA (and all subsequent country RSAs) from the ITMG to the Executive Committee. |       |                          |                  |
| Applicability:                                                                                                                                                                                            | England                                                                                                                                                      | Wales | Scotland                 | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                                                          | Yes                                                                                                                                                          | No    | Yes                      | Yes              |
| Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):                               | All                                                                                                                                                          |       | Some                     |                  |
|                                                                                                                                                                                                           |                                                                                                                                                              |       | Remove all changes below |                  |

  

|                                                                                                                                                                                                           |                                                                                                                                                                                                                                                       |       |                    |                  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|--------------------|------------------|
| Change 6                                                                                                                                                                                                  |                                                                                                                                                                                                                                                       |       |                    |                  |
| Area of change (select)*:                                                                                                                                                                                 | Project documents                                                                                                                                                                                                                                     |       |                    |                  |
| Specific area of change (select - only available when area of change is selected first)*:                                                                                                                 | IB, SmPC - non-significant changes that do not affect the risk/benefit assessment                                                                                                                                                                     |       |                    |                  |
| Further information: explain what the change is, why the change is being made and any possible impact on participants/carers (free text - note that this field will adapt to the amount of text entered): | Updated SmPCs for the simvastatin and baricitinib interventions. These are reviewed annually and the updates do not affect the risk/benefit assessment:-<br>• Simvastatin SmPC_updated 12.06.2026<br>• Baricitinib_SmPC_(Olumiant)_updated 03.06.2026 |       |                    |                  |
| Applicability:                                                                                                                                                                                            | England                                                                                                                                                                                                                                               | Wales | Scotland           | Northern Ireland |
| Where are the participating NHS/HSC organisations located that will be affected by this change?*                                                                                                          | Yes                                                                                                                                                                                                                                                   | No    | Yes                | Yes              |
| Will all participating NHS/HSC organisations be affected by this change, or only some? ( <b>please note</b> that this answer may affect the categorisation for the change):                               | All                                                                                                                                                                                                                                                   |       | Some               |                  |
|                                                                                                                                                                                                           |                                                                                                                                                                                                                                                       |       | Add another change |                  |

### Section 3: Declaration(s) and lock for submission

|                                                                                                                                                                                                                                                                |                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
| <b>Declaration by the Sponsor or authorised delegate</b>                                                                                                                                                                                                       |                                                                                                           |
| <ul style="list-style-type: none"> <li>I confirm that the Sponsor takes responsibility for the completed modification tool</li> <li>I confirm that I have been formally authorised by the Sponsor to complete the modification tool on their behalf</li> </ul> |                                                                                                           |
| <b>Applicant identification:</b>                                                                                                                                                                                                                               | <b>Sponsor</b><br>Legal representative of the sponsor<br>Person or organisation authorised by the sponsor |
| <b>Organisation:</b>                                                                                                                                                                                                                                           | Imperial College London                                                                                   |
| <b>Name [first name and surname]*:</b>                                                                                                                                                                                                                         | Nkemjika Abiakam                                                                                          |
| <b>Address:</b>                                                                                                                                                                                                                                                | Level 1 MediaWorks, 191 Wood Lane, London, W12 7FP                                                        |
| <b>Telephone number:</b>                                                                                                                                                                                                                                       |                                                                                                           |
| <b>Fax number:</b>                                                                                                                                                                                                                                             |                                                                                                           |
| <b>Purchase Order (PO) number for MHRA invoicing:</b>                                                                                                                                                                                                          | 5181872                                                                                                   |
| <b>Email address*:</b>                                                                                                                                                                                                                                         | rgit.ctimp.team@imperial.ac.uk                                                                            |

### Lock for submission

**Please note:** This button will only become available when all mandatory (\*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed modification tool which must be included in the modification submission. Please ensure that the modification tool is completed correctly before locking it for submission.

**Lock for submission**

**After locking the tool, modifications to trials processed under the combined review service should be made using the new part of IRAS. Further information can be found on the "Submission Guidance" tab.**

#### Section 4: Review bodies for the modification

**Please note:** This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

|                                       | Review bodies              |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |         |                    | Category: |         |                                |
|---------------------------------------|----------------------------|-----------------------------------------|---------------------------------------|-------|---------------------|-----------------|--------------------|-----|-------|-----------------------|------------|------|------------|--------------------------------|---------|--------------------|-----------|---------|--------------------------------|
|                                       | UK wide:                   |                                         |                                       |       |                     |                 | England and Wales: |     |       |                       | Scotland:  |      |            | Northern Ireland:              |         |                    |           |         |                                |
|                                       | REC                        | Competent Authority<br>MHRA - Medicines | Competent Authority<br>MHRA - Devices | ARSAC | Radiation Assurance | UKSW Governance | REC (MCA)          | CAG | HMPPS | HRA and HCRW Approval | REC (AWIA) | PBPP | SPS (RAEC) | National coordinating function | HSC REC | HSC Data Guardians |           | Prisons | National coordinating function |
| Change 1:                             | Y                          | Y                                       |                                       |       |                     | Y               |                    |     |       | (Y)                   |            |      |            | (Y)                            |         |                    |           | (Y)     | A                              |
| Change 2:                             | N                          | N                                       |                                       |       |                     | (Y)             |                    |     |       | (Y)                   |            |      |            | (Y)                            |         |                    |           | (Y)     | C                              |
| Change 3:                             | Y                          | Y                                       |                                       |       |                     | Y               |                    |     |       | Y                     |            |      |            | Y                              |         |                    |           | Y       | A                              |
| Change 4:                             | Y                          | Y                                       |                                       |       |                     | Y               |                    |     |       | Y                     |            |      |            | Y                              |         |                    |           | Y       | C                              |
| Change 5:                             | N                          | N                                       |                                       |       |                     | (Y)             |                    |     |       | (Y)                   |            |      |            | (Y)                            |         |                    |           | (Y)     | A                              |
| Change 6:                             | N                          | N                                       |                                       |       |                     | (Y)             |                    |     |       | (Y)                   |            |      |            | (Y)                            |         |                    |           | (Y)     | C                              |
| Overall reviews for the modification: |                            |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |         |                    |           |         |                                |
| Full review:                          | Y                          | Y                                       |                                       |       |                     | Y               |                    |     |       | Y                     |            |      |            | Y                              |         |                    |           | Y       |                                |
| Notification only:                    | N                          | N                                       |                                       |       |                     | N               |                    |     |       | N                     |            |      |            | N                              |         |                    |           | N       |                                |
| Overall modification type:            | Substantial modification   |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |         |                    |           |         |                                |
| UKSW Governance:                      | NHS/HSC review is required |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |         |                    |           |         |                                |
| Overall Category:                     | A                          |                                         |                                       |       |                     |                 |                    |     |       |                       |            |      |            |                                |         |                    |           |         |                                |

**Please note:** The modification tool has been revised to provide updated classifications in line with the new regulations. However, IRAS has not been updated and will still require you to submit using the old classifications. This section provides guidance on which option to select in order to ensure the modification is processed correctly:

Your modification should be submitted as a **substantial - project information amendment**