



Four Nations Technical Assurance Working Parties Terms of Reference

This document contains the Terms of Reference for the Four Nations Pharmacy Assurance Working Party and the Four Nations Radiation Assurance Working Party.

Contents

| | |
|--|----|
| Four Nations Pharmacy Assurance Working Party Terms of Reference..... | 3 |
| 1. Introduction..... | 4 |
| 2. Membership and Chairing | 4 |
| 3. Quorum | 4 |
| 4. Frequency of Meetings..... | 5 |
| 5. Freedom to Act..... | 6 |
| 6. Reporting..... | 6 |
| 7. Papers | 6 |
| 8. Review..... | 7 |
| 9. Appendix A: Version Control | 8 |
| Four Nations Radiation Assurance Working Party Terms of Reference..... | 10 |
| 1. Introduction..... | 11 |
| 2. Membership and Chairing | 11 |
| 3. Quorum | 11 |
| 4. Frequency of Meetings..... | 12 |
| 5. Freedom to Act..... | 13 |
| 6. Reporting..... | 13 |
| 7. Papers..... | 13 |

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| | |
|--------------------------------------|----|
| 8. Review..... | 14 |
| 9. Appendix A: Version Control | 15 |

Four Nations Pharmacy Assurance Working Party Terms of Reference

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| Document Version Number | Version 1.2 |
| Issue Date | 13 August 2020 |
| Author | Anoushka Tepielow |
| Sign-off Authority | Four Nations Pharmacy Assurance Working Party and HRA Technical Assurance Manager |
| Status | FINAL |
| Next Review date | 13 August 2021 |

1. Introduction

The Four Nations Pharmacy Assurance Working Party has been established to ensure that expert input is received in order to allow the Pharmacy Assurance project to progress as a collaborative, robust and streamlined process across the UK. The Working Party will discuss and agree upon technical aspects of the project and any problems arising, escalating any risks to each nation's respective authorities. The Working Party is accountable to the Four Nations Policy Leads Group and additionally has reporting structures within each nation:

- England – HRA Study Set-up Programme Board, HRA Approvals Oversight Group and Department of Health and Social Care
- Northern Ireland - HSC R&D Division, Public Health Agency (PHA)
- Scotland - NHS Research Scotland (NRS) and Chief Scientist Office (CSO)
- Wales – Health and Care Research Wales Change Management Group

Other management groups, in each of the nations, may be linked into for recommendations and risk review.

2. Membership and Chairing

The Four Nations Pharmacy Assurance Working Party will be chaired by the HRA Technical Assurances Manager. In the absence of the Chair, a nominated representative from the HRA may act as Chair for that meeting.

Membership of the Four Nations Pharmacy Assurance Working Party is agreed by the Working Party and ratified by the Four Nations Policy Leads Group on the recommendation of each nation's governance arrangements. The composition of the Four Nations Pharmacy Assurance Working Party and team members who are required to attend by invitation are given in [Appendix A](#).

Members may send deputies by exception only. The HRA technical assurance team will support the provision of the secretariat function for this Working Party.

3. Quorum

A quorum shall consist of three expert members from any of the participating nations, all of which must be external to the Health Research Authority. Where an expert member is unable to attend, a nominated deputy may attend on their behalf. The deputy's information (to include name and role) must be submitted to either the Chair or Secretariat prior to the meeting commencing.

The Secretariat must advise the Chair or their deputy if there is risk of the meeting being inquorate. It is the responsibility of the Secretariat to know what the quoracy requirements are and must have this information available prior to the Four Nations

Document date: 25 August 2020

Pharmacy Assurance Working Party meeting so that the Chair is able to make a decision as to whether the meeting should go ahead.

If the meeting is inquorate, and/or both the Chair and their deputy are not in attendance, the meeting can go ahead as planned and minutes are taken. However, any decisions or actions taken at the meeting must be ratified either at the next meeting or out of session if urgent.

4. Frequency of Meetings

Meetings will be held monthly usually by teleconference. Ad hoc meetings, or informal sub-group meetings, may be held by agreement of the Chair as and when required so that the work can continue at pace. Meetings may, exceptionally, be cancelled by the Chair.

There may occasionally be a need for Chair's action in order to finalise matters which have already been discussed. Any Chair's action taken between meetings are to be recorded in the minutes of the next meeting.

The Four Nations Pharmacy Assurance Working Party will be responsible for providing advice on the development, delivery and roll out of Pharmacy Assurance UK-wide. Specifically it will:

- Advise on the strategic direction for the further development and implementation of Pharmacy Assurance across the UK.
- Agree and advise on key technical principles and processes for Pharmacy Assurance implementation, taking into consideration UK-wide systems. Advice may also be given on operational aspects of the project.
- Receive and review reports from the HRA technical assurance team on the progress of the project, ensuring management and mitigation of risks, providing feedback, support and challenge as appropriate.
- Work with the Four Nations Policy Leads Group and project boards and/or teams within the HRA to ensure a single direction of project development, reduce conflicting actions and minimise any duplication of resources. The Four Nations Pharmacy Assurance Working Party may discuss matters for which decision making responsibility lies elsewhere and these should be taken to the appropriate decision making body by the Chair.
- Report to the relevant UK groups on the progress of the project. This includes, but is not limited to the:
 - Four Nations Policy Leads Group
 - HRA Study Set-up Programme Board (reports to this Board will be made monthly)
 - Northern Ireland - HSC R&D Division, PHA
 - Scotland – NRS / CSO

Document date: 25 August 2020

- Wales – Health and Care Research Wales Change Management Group
- Review the risks associated with the project, escalating to each Nation's respective authorities, along with any proposals for changes to plans, priorities or resources that would address identified risks.

HRA technical assurance team members attending the meetings, most especially the Technical Assurances Manager, have a specific role to play in ensuring consistency across the HRA project boards and/or teams and identifying matters that have fallen between the responsibilities of the boards and/or teams.

5. Freedom to Act

The Four Nations Pharmacy Assurance Working Party has the authority to modify plans or alter priorities within this workstream only where there are no interdependencies to plans or priorities for other workstreams, or where failure to modify plans or priorities would put the programme delivery at risk. The Four Nations Pharmacy Assurance Working Party does however have the authority to propose changes to plans and priorities to the Four Nations Policy Leads Group and has a responsibility to do so and to highlight identified interdependencies with other workstreams. The Four Nations Pharmacy Assurance Working Party does not have the authority to add or remove resources allocated to the workstream but has a responsibility to propose changes to the Four Nations Policy Leads Group. The Four Nations Pharmacy Assurance Working Party cannot authorise expenditure but has a responsibility to propose requirements to each nation's respective authorities.

6. Reporting

The Four Nations Pharmacy Assurance Working Party will report to each nation's respective authorities and to the Four Nations Policy Leads Group. Each national authority will have its own mechanism for escalating issues, for example, in England issues may be drawn to the attention of the HRA Transformation Board, to the HRA Leadership Team and/or HRA Board.

The minutes of these meetings will be formally recorded and available to the relevant respective authorities upon request. When approved by the Four Nations Pharmacy Assurance Working Party the minutes will be made available on the HRA shared drive. Occasionally, when the minutes contain information that it is not in the public interest to publish, this content will be contained within a part 2 section of the minutes which is confidential.

7. Papers

Agenda items may be raised by any member of the Working Party and should be communicated to the secretariat at least seven working days in advance of any meeting.

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All papers for the Working Party meetings will be circulated to Working Party members at least five working days in advance of meetings.

Draft minutes of each meeting will be circulated within seven working days to Working Party members for comment and will provide a clear record of decisions reached and actions agreed.

Minutes will be formally approved by the Working Party at the subsequent meeting.

The secretariat will maintain an action log, which will be circulated to Working Party members within seven days of a meeting occurring. These will also be reviewed at each meeting.

It is expected that members will not circulate papers outside of the Working Party without prior agreement from the HRA.

8. Review

The terms of reference should be reviewed at least annually.

9. Appendix A: Version Control

Origin and responsibility

Author: Anoushka Tepielow

Project Name: Four Nations Pharmacy Assurance

Change history

| Version and status | Changes |
|--------------------|--|
| 0.1 DRAFT | Document creation |
| 0.2 DRAFT | Clarifying roles of members and reporting arrangements |
| 0.3 DRAFT | Spelling and grammatical changes |
| 0.4 DRAFT | Amending internal HRA reporting arrangements Clarifying Working Party composition Grammatical changes |
| 1.0 FINAL | Up-versioning to final version for publication on HRA website |
| 1.1 FINAL | Clarification of management of document sharing arrangements Amendments to ensure the document is in an accessible format |
| 1.2 FINAL | Amending internal HRA reporting arrangements |

Working Party composition

| Role | Job Title |
|---|---|
| Chair | Manager – Technical Assurances |
| Pharmacy Expert Representative - Wales | Principal Pharmacist Research, Development and Audit |
| Pharmacy Expert Representative - Scotland | Lead Pharmacist Clinical Trials |
| Pharmacy Expert Representative – Northern Ireland | Lead Clinical Trials Pharmacist, Belfast Health and Social Care Trust (BHSCT) |

Document date: 25 August 2020

| Role | Job Title |
|-----------------------------------|--|
| | Chairperson, Northern Ireland, Regional Pharmacy Clinical Trials Group |
| Pharmacy Expert Advisor - England | Lead Clinical Trials Pharmacist |
| Secretariat (in attendance only) | Technical Assurance Officer |

Distribution and publication

This document will be published externally on the HRA website and will be available internally on the HRA shared drive.

Four Nations Radiation Assurance Working Party Terms of Reference

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|--------------------------------|--|
| Document Version Number | Version 1.2 |
| Issue Date | 25 August 2020 |
| Author | Anoushka Tepielow |
| Sign-off Authority | Four Nations Radiation Assurance Working Party and HRA Technical Assurance Manager |
| Status | FINAL |
| Next Review date | 25 August 2021 |

1. Introduction

The Four Nations Radiation Assurance Working Party has been established to ensure that expert input is received in order to allow the Radiation Assurance project to progress as a collaborative, robust and streamlined process across the UK. The Working Party will discuss and agree upon technical aspects of the project and any problems arising, escalating any risks to each nation's respective authorities. The Working Party is accountable to the Four Nations Policy Leads Group and additionally has reporting structures within each nation:

- England – HRA Study Set-up Programme Board, Approvals Oversight Group, and Department of Health and Social Care
- Northern Ireland – HSC Research and Development Division, Public Health Agency
- Scotland – NHS Research Scotland and Chief Scientist Office (CSO)
- Wales – Health and Care Research Wales Change Management Group

Other management groups in each of the nations may be linked into for recommendations and risk review.

The HRA technical assurance team will coordinate and lead on the project.

2. Membership and Chairing

The Four Nations Radiation Assurance Working Party will be chaired by the HRA Technical Assurances Manager. In the absence of the Chair, a nominated representative from the HRA may act as Chair for that meeting.

Membership of the Four Nations Radiation Assurance Working Party is agreed by the Working Party and ratified by the Four Nations Policy Leads Group on the recommendation of each nation's governance arrangements. The composition of the Four Nations Radiation Assurance Working Party and team members who are required to attend by invitation are given in [Appendix A](#).

Members may send deputies by exception only. The HRA technical assurance team will support the provision of the secretariat function for this Working Party.

3. Quorum

A quorum shall consist of three expert members from any of the participating nations, all of which must be external to the Health Research Authority. Where an expert member is unable to attend, a nominated deputy may attend on their behalf. The deputy's information (to include name and role) must be submitted to either the Chair or Secretariat prior to the meeting commencing.

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The Secretariat must advise the Chair or their deputy if there is risk of the meeting being inquorate. It is the responsibility of the Secretariat to know what the quoracy requirements are and must have this information available prior to the Four Nations Radiation Assurance Working Party meeting so that the Chair is able to make a decision as to whether the meeting should go ahead.

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4. Frequency of Meetings

Meetings will be held monthly usually by teleconference. Ad hoc meetings, or informal sub-group meetings, may be held by agreement of the Chair as and when required so that the work can continue at pace. Meetings may, exceptionally, be cancelled by the Chair.

There may occasionally be a need for Chair's action in order to finalise matters which have already been discussed. Any Chair's action taken between meetings are to be recorded in the minutes of the next meeting.

The Four Nations Radiation Assurance Working Party will be responsible for providing advice on the development, delivery and roll out of Radiation Assurance UK-wide. Specifically it will:

- Advise on the strategic direction for the further development and implementation of Radiation Assurance across the UK.
- Agree and advise on key technical principles and processes for the Radiation Assurance implementation, taking into consideration UK-wide systems. Advice may also be given on operational aspects of the project.
- Receive and review reports from the HRA technical assurance team on the progress of the project ensuring management and mitigation of risks, providing feedback, support and challenge as appropriate.
- Work with the Four Nations Policy Leads Group and project boards and/or teams within the HRA to ensure a single direction of project development, reduce conflicting actions and minimise any duplication of resources. The Four Nations Radiation Assurance Working Party may identify matters for which decision making responsibility lies elsewhere and these should be taken to the appropriate decision making body by the Chair.
- Report to the relevant UK groups on the progress of the project. This includes, but is not limited to the:
 - Four Nations Policy Leads Group
 - HRA Study Set-up Programme Board (report to this Board will be made monthly)

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- ARSAC (Department of Health and Social Care – Policy)
- HSC Research and Development Division, Public Health Agency
- NHS Research Scotland / CSO (Chief Scientist Office)
- Health and Care Research Wales Change Management Group
- Review the risks associated with the project, escalating to each nation's respective authorities, along with any proposals for changes to plans, priorities or resources that would address identified risks.

HRA technical assurances team members attending the meetings, most especially the Technical Assurance Manager, have a specific role to play in ensuring consistency across the HRA project boards and/or teams and identifying matters that have fallen between the responsibilities of the boards.

5. Freedom to Act

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8. Review

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9. Appendix A: Version Control

Origin and responsibility

Author: Anoushka Tepielow

Project Name: Four Nations Radiation Assurance

Change history

| Version and status | Changes |
|--------------------|---|
| V0.1 DRAFT | Document creation |
| V0.2 DRAFT | Clarification throughout on governance arrangements |
| V0.3 DRAFT | Clarification of members and their roles |
| V0.4 DRAFT | Amending reporting arrangements in Northern Ireland |
| V0.5 DRAFT | Amending internal HRA reporting arrangements Clarifying Working Party composition Grammatical changes |
| V1.0 FINAL | Up-version to final version for publication on HRA website |
| V1.1 FINAL | Addition of CRE Expert Advisor Clarification of management of document sharing arrangements |
| V1.2 FINAL | Amending internal HRA reporting arrangements |

Working Party composition

| Role | Job Title |
|-------------------------------------|--------------------------------------|
| Chair | Manager – Technical Assurances |
| Wales MPE representative | Head of Radiation Protection Service |
| Scotland MPE representative | Head of Radiation Protection |
| Northern Ireland MPE representative | Head Radiological Sciences & Imaging |

Document date: 25 August 2020

| Role | Job Title |
|----------------------------------|---|
| England MPE Expert Advisor | Head of Radiology Physics |
| CRE Expert Advisor | Professor of Cancer Imaging and Radiology |
| ARSAC representative | Scientific Advisor |
| Secretariat (in attendance only) | Technical Assurance Officer |

Distribution and Publication

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