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| **Agenda item:** | **13** |
| **Attachment:** | **J** |

**HRA BOARD COVER SHEET**

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| **Date of Meeting:** | 17 February 2016 |

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| **Title of Paper:** | Evaluation of the Radiation Technical Assurance pilot undertaken in collaboration with Cancer Research UK and the UK Experimental Cancer Medicine Centres |
| **Purpose of Paper:** | To evaluate the pilot testing period of the Radiation Technical Assurance |
| **Reason for Submission:** | For information |
| **Details:** | **Key Achievements**   * Development and testing of a robust process for ensuring the availability of expert review on radiation aspects of a study and agreement on preferred risk statements for application and patient facing documentation * Ongoing refinements to the process were made during testing to ensure it is viable for all stakeholders * A timeline which is workable for the HRA, sponsors and reviewers has been shown to be feasible * Development of key supporting documents to ensure consistency within the process * Production of guidance for reviewers and sites by current expert radiation reviewers   **Next Steps**   * Initiate phased roll out of Radiation Assurance Process * Recruit reviewers in step with phased roll out to support increase in study numbers * Ensure the reviewers are professionally supported and the process has continuing expert input * Test the guidance which has been produced, including consultation in use of the Generic Risk Statements * Establish a system of continual refinement of the process with more studies and agree feasible metrics and timelines * Collaboration with the Devolved Administrations to ensure compatibility |
| **Time required for item:** | **15** |

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| **Recommendation / Proposed Actions:** | **To Approve** | |  |
| **To Note** | | **x** |
| **For Discussion** | | **x** |
| **Comments** |  | |

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| **Name:** | Janet Messer |
| **Job Title:** | Director of Research Systems, Standards & HRA Approval Programme |
| **Date:** | 10/02/2016 |