Guidance for developing and submitting an Inclusion and Diversity Plan

Reference document prepared from HRA and MHRA published guidance and the pilot findings summary

Health Research Authority (HRA), United Kingdom, in collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA)

Document type	Regulatory guidance — reference summary
Last updated	2 November 2026 (HRA guidance and pilot findings pages)
Status	Current guidance; submission of a Plan is voluntary
Jurisdiction	United Kingdom

Purpose of the Inclusion and Diversity Plan

The HRA and MHRA recommend that sponsors and researchers develop an Inclusion and Diversity Plan early in the study design process. The purpose is to help ensure that clinical research is designed to include people who could be affected by the findings and that groups often under-served by research are not overlooked. Considering inclusion during study design can help research populations and recruitment approaches to be appropriately justified.

The Plan is structured around four central questions:

Q1. Who is affected by the disease or condition being studied?

Q2. Do the aims and design of the research mean that the findings will be generalisable to all groups identified in Q1? If not, why?

Q3. What are the recruitment goals?

Q4. What is the plan to recruit and retain the proposed study population?

Scope and applicability

The guidance is intended for sponsors and researchers planning clinical trials or clinical investigations, including:

• clinical trials of investigational medicinal products (CTIMPs);
• clinical investigations or other studies of medical devices;
• combined trials of an investigational medicinal product and an investigational medical device;
• other clinical trials studying a novel intervention or randomised clinical trials comparing interventions in clinical practice.

Observational studies are outside the scope of the guidance.

The Plan may be prepared for an individual study or for a product development programme, with the information relevant to the particular study clearly identified. Inclusivity should be considered from the earliest stages of product development, including the justification for populations excluded from early-phase studies.

Submission and regulatory handling

Submission of an Inclusion and Diversity Plan is voluntary; the HRA encourages sponsors and researchers to submit one alongside an application for approval. Depending on the study type, the Plan may be submitted through the relevant part of the Integrated Research Application System

(IRAS).

Research Ethics Committees (RECs) use the information in the Plan to inform their understanding of the overall application and to support discussion where ethical issues arise. The Plan is not a standalone submission document directly assessed as part of a clinical trial authorisation application.

The absence of a Plan will not, by itself, result in an application being rejected or receiving an unfavourable ethical opinion. If the Plan raises questions about study design, the REC may ask the applicant about those matters as part of its review of the overall application.

MHRA GCP inspectors do not inspect how the Plan was developed, written or approved, or whether the Plan itself has been followed. However, aspects of the Plan reflected in other application documents, such as the clinical protocol, may be subject to routine inspection.

If a Plan is changed after review, it does not need to be resubmitted; the HRA recommends documenting updates and retaining records.

Pilot and implementation phase

The HRA and MHRA launched a pilot in May 2025, inviting sponsors and researchers to develop a Plan and submit it as part of an overall application review by a Research Ethics Committee. The pilot formally closed at the end of 2025. Seven studies took part: five from commercial sponsors and two from non-commercial sponsors.

Commercial sponsors reported that developing a Plan helped them consider inclusion and diversity in a more structured way and, in some cases, supported recruitment discussions with study sites. Feedback from REC members was mixed. It highlighted the burden of reviewing an additional document, duplication of information already provided elsewhere, and differing views on how information should be presented to committees.

Access to reliable UK-specific epidemiological data was identified as a significant challenge in preparing Plans. The pilot also highlighted the need for clearer guidance on early-phase and rare-disease studies and on the level of detail RECs need to see.

An implementation phase is planned to begin in early 2027. During this phase, more sponsors and researchers will be invited to submit Plans voluntarily alongside applications, with feedback collected over a 12-month period through a small number of participating RECs.

Intended audience

The guidance is relevant to sponsors, clinical researchers, study teams and organisations preparing clinical trial or clinical investigation applications in the United Kingdom. It is also relevant to Research Ethics Committees considering the information provided in a Plan.

Source and document status

This reference PDF has been prepared to correspond to the approved TP-DOC-007 Summary. It brings together relevant content from the HRA guidance page and the HRA/MHRA pilot findings summary. It is an independently prepared reference copy and is not an official PDF issued by the HRA or MHRA.

Primary guidance source: Health Research Authority — Guidance for developing and submitting an Inclusion and Diversity Plan.
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/increasing-diversity-people-taking-part-research/guidance-for-developing-and-submitting-an-inclusion-and-diversity-plan/
Pilot findings source: Health Research Authority — The HRA and MHRA inclusion and diversity pilot findings summary.
https://www.hra.nhs.uk/about-us/news-updates/the-hra-and-mhra-inclusion-and-diversity-pilot-findings-summary/

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