Please see below for a link to the webinar recording for the Trials Methodology Research Partnership:

**SPIRIT-ROUTINE**

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On behalf of the HRB Trials Methodology Research Network

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[https://www.youtube.com/watch?v=KZbdAyTq_dI](https://www.youtube.com/watch?v=KZbdAyTq_dI)
SPIRIT-ROUTINE: Developing a SPIRIT extension for trials conducted using cohorts and routinely collected data

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SPIRIT-ROUTINE Team
Information in clinical trial protocols may be incomplete or inadequate

In 2007, an international group of stakeholders (the SPIRIT Group) launched the SPIRIT initiative to help improve the completeness and quality of trial protocols. SPIRIT guidance has been instrumental in promoting transparent evaluation of new interventions.

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SPIRIT Extensions


- Trials are expensive and complex

- Increasing interest in use of Routinely Collected Data (RCD) in trials
  - Improve participant recruitment
  - Improve generalisability of findings
  - Simplify assessment of outcome measures
Aim

• Develop, test, and disseminate an extension of the SPIRIT reporting guidelines for the minimum content of clinical trial protocols for trials using Routinely Collected Data

This project is complete, well described and proposed appropriate methods to achieve research goal.

but we deplore the absence of PPI, as it was requested.

No early career individuals specified which is a shame as developing guidance is a great skill for an ECR to adopt.
SPIRIT – Routine Process

1. Project launch - Agree definition of RCD
2. Rapid review - identify protocols
3. Online Delphi - methods and content experts
4. Steering committee meeting - finalise items in SPIRIT extension
5. Disseminate & implement final checklist
A project operational team and a study steering committee was established to deliver the project aims.
EQUATOR Registration

- Registration of SPIRIT-ROUTINE with Enhancing the QUAlity and Transparency Of health Research (EQUATOR) library of reporting guidelines
Agreement on Scope of the Extension

- Specified and agreed consensus definition of Routinely Collected Data in trials:

  Routinely collected data (RCD) refers to data collected for purposes other than research
Stage 1

- Publication of study protocol in HRB Open Research

**STUDY PROTOCOL**

A study protocol for the development of a SPIRIT extension for trials conducted using cohorts and routinely collected data (SPIRIT-ROUTINE) [version 1; peer review: awaiting peer review]


**PEER REVIEWERS Invited**

**FUNDERS**
- Medical Research Council
- National Institute for Health Research (NIHR) Biomedical Research Centre
- UK Research & Innovation Future Leaders Fellowship
- Wellcome Trust
- Health Research Board Trials Methodology Research Network

**PUBLISHED 29 Jul 2021**
A search of the US National Library of Medicine’s clinical trial registry (ClinicalTrials.gov) was undertaken to find trial protocols using cohorts and RCD in Canada and the US (National Institute of Health (NIH) funded US trials).

A similar search of the National Institutes of Health Research (NIHR) journals library in the UK was also undertaken.

Inclusion criteria:
✓ RCT of any type
✓ use of cohorts and RCD; and
✓ availability of a protocol

Search results were individually downloaded into the citation management database Mendeley, and duplicates were removed.
Rapid Review

1. Records identified through database searching (n = 1,584)
2. Additional records identified through other sources (n = 0)
3. Records after duplicates removed (n = 24)
4. Records screened (n = 1,560)
5. Records Excluded: 511
   - Non-RCT (n=447)
   - No protocol (n= 47)
   - Unclear if protocol available (n=17)
6. Protocols assessed for eligibility (n = 1,049)
7. Protocols included (n = 181)
8. Protocols Excluded
   - RCTs that do not use RCD (N=868)
Potential new items/modifications

• Trial protocols that described aspects of methods or reporting of trials conducted using cohorts or RCD, were examined

• Areas of trial design considered important to report identified

• Potential items applicable to trials using cohorts or RCD which clarified or altered an existing SPIRIT 2013 item (modifications)

• Preliminary ‘long list’ of possible new reporting items was also formulated based on review of the SPIRIT 2013 statement items and the CONSORT-ROUTINE items
### Potential new items/modifications

#### Table: Existing SPIRIT Items and Proposed Modifications and New Items for SPIRIT-Routine Extension

<table>
<thead>
<tr>
<th>Item</th>
<th>SPIRIT 2013 Statement</th>
<th>SPIRIT-ROUTINE Extension</th>
<th>CONSORT-ROUTINE Items AND modified CONSORT-ROUTINE Items (to fit with SPIRIT-Routine Items)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>1. Descriptive title (identifying the study design, population, interventions, and, if applicable, trial name)</td>
<td>3. Descriptive title (identifying the study design or the relatively collected datasets used to conduct the trial, population, interventions, and, if applicable, trial name)</td>
<td></td>
</tr>
<tr>
<td><strong>Trial Registration</strong></td>
<td>2a. Trial identifier and registry name, if trial yet registered, name of intended registry.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Protocol Version</strong></td>
<td>2b. All items from the World Health Organization Trial Registration Data Set.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Delphi

- Evaluate the list of items for consideration to be included in the SPIRIT-ROUTINE extension
- Identify additional items that may not have been identified in the review

- COMET DelphiManager software
- Participants: clinical trialists, trial methodologists, guideline experts, TMRN members and PPI contributors
- Rate items based on how valuable they are for the reporting of trial protocols on a Likert scale of 1–9:
  - 1-3 = ‘not critical’ (items should not be part of the SPIRIT-ROUTINE extension checklist)
  - 4–6 = ‘no consensus’ (items should be discussed)
  - 7–9 = ‘critical to include’ (item should be part of SPIRIT-ROUTINE extension checklist)
Consensus Meeting

- Presentation of items by individuals with expertise, followed by a discussion
- The items in the Delphi survey which reached consensus will be discussed, followed by any possible objections
- Outstanding items will be examined, and meeting participants will be provided with the opportunity to discuss each item
- Participants will be provided with the opportunity to discuss any items excluded during the Delphi process and will be able to propose better explanations of any excluded items
- Items with >75% or more of voters voting for its inclusion will be retained.
Dissemination and Knowledge translation

Strategies for knowledge translation will include:

1. Publication of the SPIRIT-ROUTINE extension in journals
2. Dissemination via the SPIRIT group and EQUATOR network, including publication on their websites
3. Presentations at conferences (e.g. submission to ICTMC 2022) and focused workshops on trials embedded in existing data sources
4. Dissemination via the TMRN and TMRP with delivery of a Clinical Research Facility-Cork (CRF C/TMRN) webinar on the process of the development of a SPIRIT extension
5. Dissemination will include presentation at the HRB-TMRN webinar and through relevant social media channels such as Twitter and YouTube
SPIRIT Routine

- Valuable to researchers who are planning to design a study using RCD
- May optimize the use of RCD in clinical trials
- Standardise what is expected in protocols of clinical trials using RCD
- Improve access to trial data and efficiency of data access. Help improve the transparency and quality of clinical trial protocols and reports of trials using RCD
SPIRIT Routine

• This SPIRIT-ROUTINE extension for trials conducted using cohorts and RCD aims to promote transparency and clarity and to reduce research waste due to inadequate reporting.

• Consistent with the recently developed CONSORT extension for trials conducted using cohorts and RCD, this SPIRIT extension is being carried out with the long-term goal of improving the quality of reporting by establishing standards early in the process of uptake of these trial designs.


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Thank You!

Any Questions?

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