Development of SPIRIT-CONSORT surrogate extensions

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Disclosures

- No personal conflicts
- Development of SPIRIT/CONSORT extensions funded by UK Medical Research Council (grant number MR/V038400/1

Reporting Guideline Development

OPEN ACCESS Freely available online

PLoS MEDICINE

Guidelines and Guidance

Guidance for Developers of Health Research Reporting Guidelines

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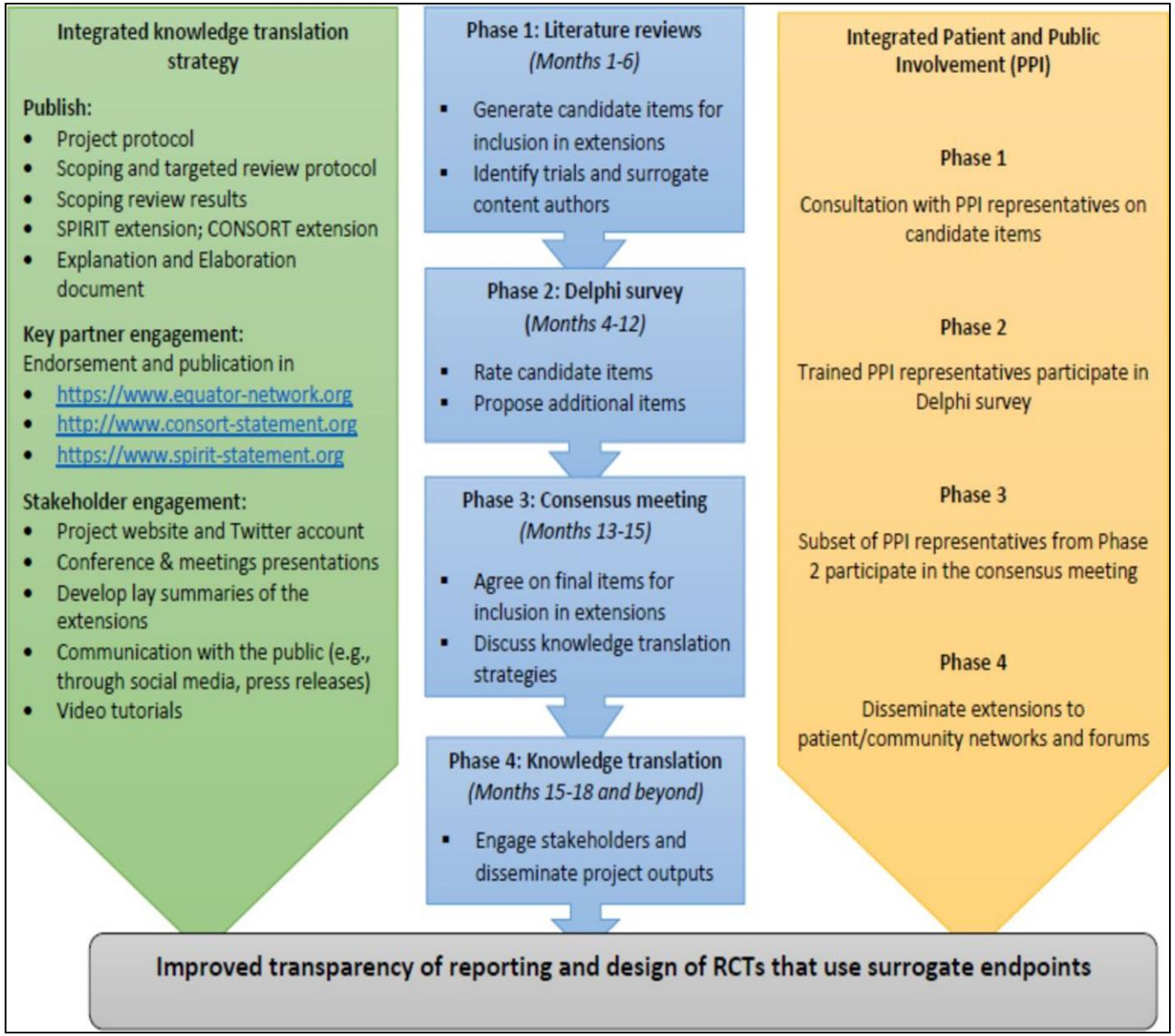
Randomised trials CONSORT Extensions

Observational



Phase 1: Literature reviews

- **Scoping review**
  - Definitions
  - Acceptability
  - Limitations
  - Guidance/advice in design and reporting
- Data from 90 records synthesised into 17 candidate items

ELSEVIER

Journal of Clinical Epidemiology
Volume 160, August 2023, Pages 83-99

Review Article

Definitions, acceptability, limitations, and guidance in the use and reporting of surrogate end points in trials: a scoping review

Anthony Muchai Manyara [a], Philippa Davies [b], Derek Stewart [c], Christopher J. Weir [d], Amber E. Young [b], Valerie Wells [a], Jane Blazeby [b e f], Nancy J. Butcher [g h], Sylwia Bujkiewicz [i], An-Wen Chan [j k], Gary S. Collins [l], Dalia Dawoud [m], Martin Offringa [g n], Mario Ouwens [o], Joseph S. Ross [p q], Rod S. Taylor [a r], Oriana Ciani [s]

Phase 1: Literature reviews

- **Targeted review**
  - ~3500 trials and protocols published in last 5 years identified
  - 1400 trial authors invited to participate in the Delphi survey
  - Synthesis of the completeness of reporting in protocols and reports using surrogate primary endpoints

Phase 2: e-Delphi survey

- 212 registered and were eligible
  - 195 (92%) rated items in Round 1, 176 (83%) in Round 2
- Representation from 31 countries & >26 clinical/research areas
- Multistakeholder effort:
  - Clinicians, trial investigators, methodologists, statisticians, PPI partners, HTA experts, funding panel members, surrogate content experts, journal editors, regulatory assessor, ethics committee members, funding panel members
- Round 1 open from 24th August to 10th October 2022; and Round 2: 31st October to 11th December 2022.

Consensus definition

- As per the project protocol, consensus was defined as follows:
  - Consensus for inclusion: ≥70% participants scoring 7-9 and <15% participants scoring 1-3
  - Consensus for exclusion: ≥70% participants scoring 1-3 and <15% of participants scoring 7-9
  - No consensus for inclusion or exclusion: failure to achieve both the above

Rated items and consensus

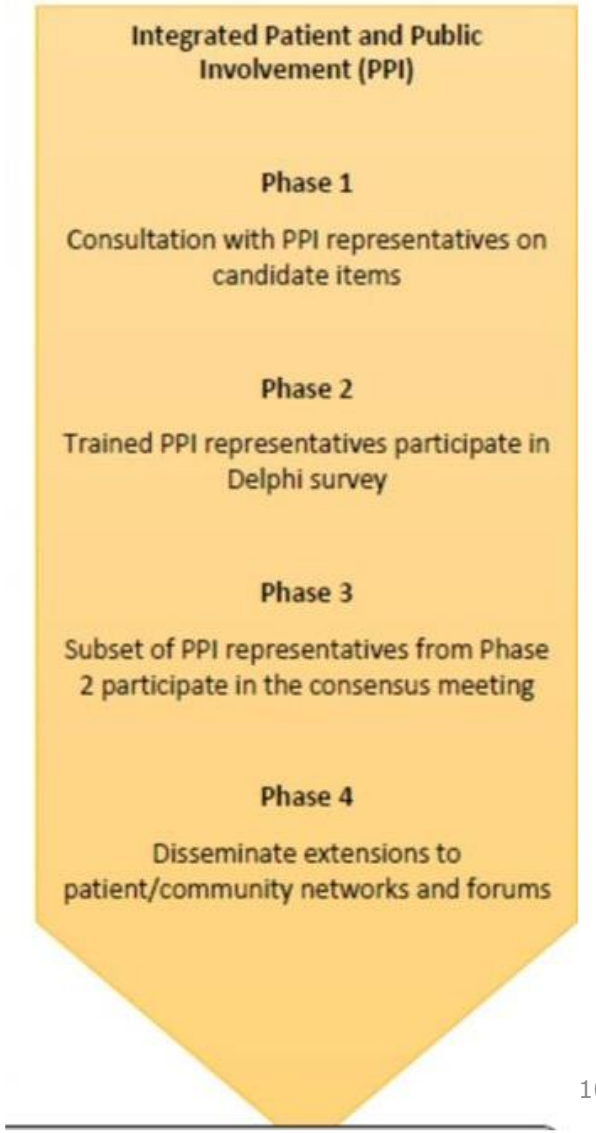
- The 17 items identified from scoping review refined to 13 CONSORT items and 9 SPIRIT items
  - Rating for CONSORT and SPIRIT items done in a single Delphi survey
  - One more item for both CONSORT and SPIRIT added in Round 2
- **10 CONSORT and 7 SPIRIT items** achieved consensus for inclusion after Delphi Round 2
- 4 CONSORT and 3 SPIRIT items did not reach consensus – discussed in Consensus meeting

Consensus meeting

- Hybrid meeting on 13th-14th March 2023
- 33 delegates (10 in Glasgow + 23 virtual), 4 observers
- Discussion and vote on 3 for SPIRIT and 4 for CONSORT items
- Consensus: 5 for inclusion and 2 for exclusion
- Fine tune items that reached consensus for inclusion

Integration of PPI in the project

- Virtual learning workshop on 15th August 2022
- 19 PPI partners attended
- Interactive learning on what are surrogate endpoints and project rationale
- Most of PPI partners attending workshop participated in Delphi survey
- Four joined the Consensus Meeting



Phase 4: Knowledge translation

Integrated knowledge translation strategy

Publish:

- Project protocol
- Scoping and targeted review protocol
- Scoping review results
- SPIRIT extension; CONSORT extension
- Explanation and Elaboration document

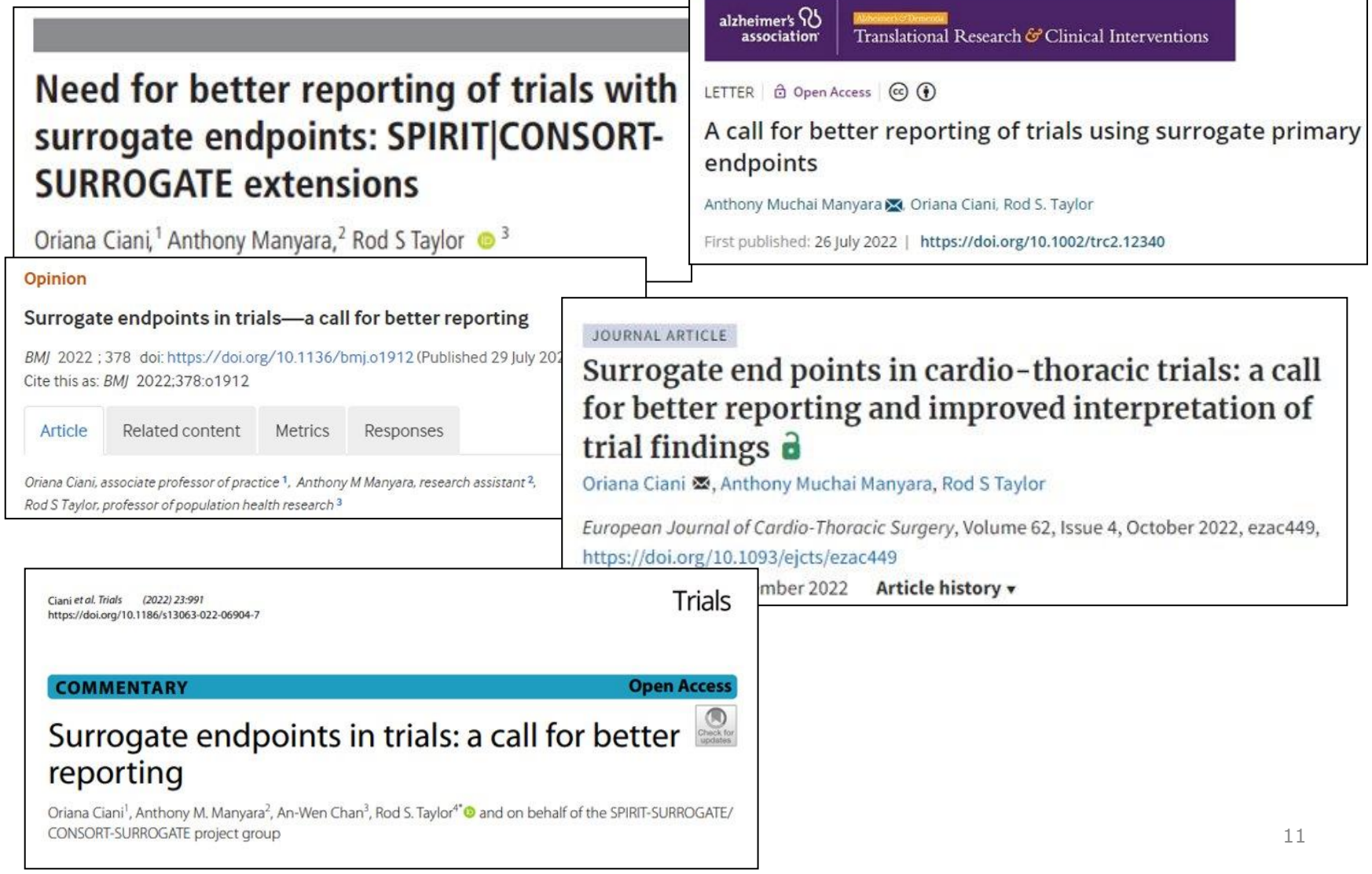
Key partner engagement:

Endorsement and publication in

- https://www.equator-network.org
- http://www.consort-statement.org
- https://www.spirit-statement.org

Stakeholder engagement:

- Project website and Twitter account
- Conference & meetings presentations
- Develop lay summaries of the extensions
- Communication with the public (e.g., through social media, press releases)
- Video tutorials



Need for better reporting of trials with surrogate endpoints: SPIRIT|CONSORT-SURROGATE extensions

Oriana Ciani,[1] Anthony Manyara,[2] Rod S Taylor [3]

alzheimer's association | Translational Research & Clinical Interventions

LETTER | Open Access

A call for better reporting of trials using surrogate primary endpoints

Anthony Muchai Manyara, Oriana Ciani, Rod S. Taylor

First published: 26 July 2022 | https://doi.org/10.1002/trc2.12340

Opinion

Surrogate endpoints in trials—a call for better reporting

BMJ 2022 ; 378 doi: https://doi.org/10.1136/bmj.o1912 (Published 29 July 202

Cite this as: *BMJ* 2022;378:o1912

Article | Related content | Metrics | Responses

Oriana Ciani, associate professor of practice [1], Anthony M Manyara, research assistant [2], Rod S Taylor, professor of population health research [3]

JOURNAL ARTICLE

Surrogate end points in cardio-thoracic trials: a call for better reporting and improved interpretation of trial findings

Oriana Ciani, Anthony Muchai Manyara, Rod S Taylor

European Journal of Cardio-Thoracic Surgery, Volume 62, Issue 4, October 2022, ezac449, https://doi.org/10.1093/ejcts/ezac449

mber 2022 **Article history**

Ciani *et al. Trials* (2022) 23:991 https://doi.org/10.1186/s13063-022-06904-7

Trials

COMMENTARY Open Access

Surrogate endpoints in trials: a call for better reporting

Oriana Ciani[1], Anthony M. Manyara[2], An-Wen Chan[3], Rod S. Taylor[4*] and on behalf of the SPIRIT-SURROGATE/CONSORT-SURROGATE project group

Open access Protocol

BMJ Open

Scoping and targeted reviews to support development of SPIRIT and CONSORT extensions for randomised controlled trials with surrogate primary endpoints: protocol

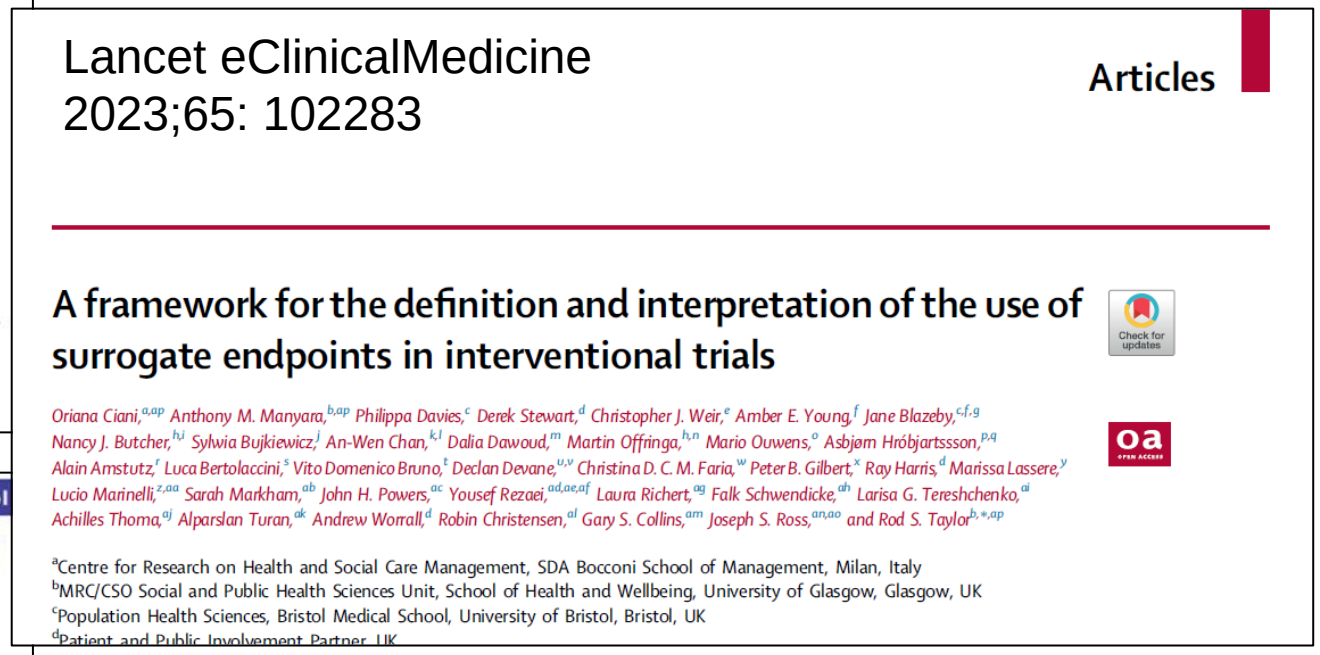
Anthony Muchai Manyara ,[1] Philippa Davies,[2] Derek Stewart,[3] Valerie Wells,[1] Christopher Weir ,[4] Amber Young ,[2] Rod Taylor,[1,5] Oriana Ciani[6]

Open access Protocol

BMJ Open

Protocol for the development of SPIRIT and CONSORT extensions for randomised controlled trials with surrogate primary endpoints: SPIRIT-SURROGATE and CONSORT-SURROGATE

Anthony Muchai Manyara ,[1] Philippa Davies,[2] Derek Stewart,[3] Christopher J Weir ,[4] Amber Young ,[2] Nancy J Butcher ,[5,6] Sylwia Bujkiewicz,[7] An-Wen Chan,[8,9] Gary S Collins ,[10] Dalia Dawoud,[11] Martin Offringa ,[6] Mario Ouwens,[12] Joseph S Ross,[13,14] Rod S Taylor,[1,15] Oriana Ciani[16]



Lancet eClinicalMedicine
2023;65: 102283

Articles

A framework for the definition and interpretation of the use of surrogate endpoints in interventional trials

Oriana Ciani,[a,ap] Anthony M. Manyara,[b,ap] Philippa Davies,[c] Derek Stewart,[d] Christopher J. Weir,[e] Amber E. Young,[f] Jane Blazeby,[c,f,g] Nancy J. Butcher,[h,i] Sylwia Bujkiewicz,[j] An-Wen Chan,[k,l] Dalia Dawoud,[m] Martin Offringa,[h,n] Mario Ouwens,[o] Asbjørn Hróbjartssson,[p,q] Alain Amstutz,[r] Luca Bertolaccini,[s] Vito Domenico Bruno,[t] Declan Devane,[u,v] Christina D. C. M. Faria,[w] Peter B. Gilbert,[x] Ray Harris,[d] Marissa Lassere,[y] Lucio Marinelli,[z,aa] Sarah Markham,[ab] John H. Powers,[ac] Yousef Rezaei,[ad,ae,af] Laura Richert,[ag] Falk Schwendicke,[ah] Larisa G. Tereshchenko,[ai] Achilles Thoma,[aj] Alparslan Turan,[ak] Andrew Worrall,[d] Robin Christensen,[al] Gary S. Collins,[am] Joseph S. Ross,[an,ao] and Rod S. Taylor[b,*,ap]

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