

Ottawa Group

Principles of operationalisation of results reporting

27th October 2006
Dublin, Ireland

Ottawa Statement 1

A. Objective

The Ottawa Statement aims to establish internationally recognised the principles for trial registration (Part 1), operationalisation (Part 2), and the principles of results reporting (Part 3).

Ottawa group meeting on operationalisation of results reporting 27 October 2006

AGENDA

- Timing
- Venue
- Content

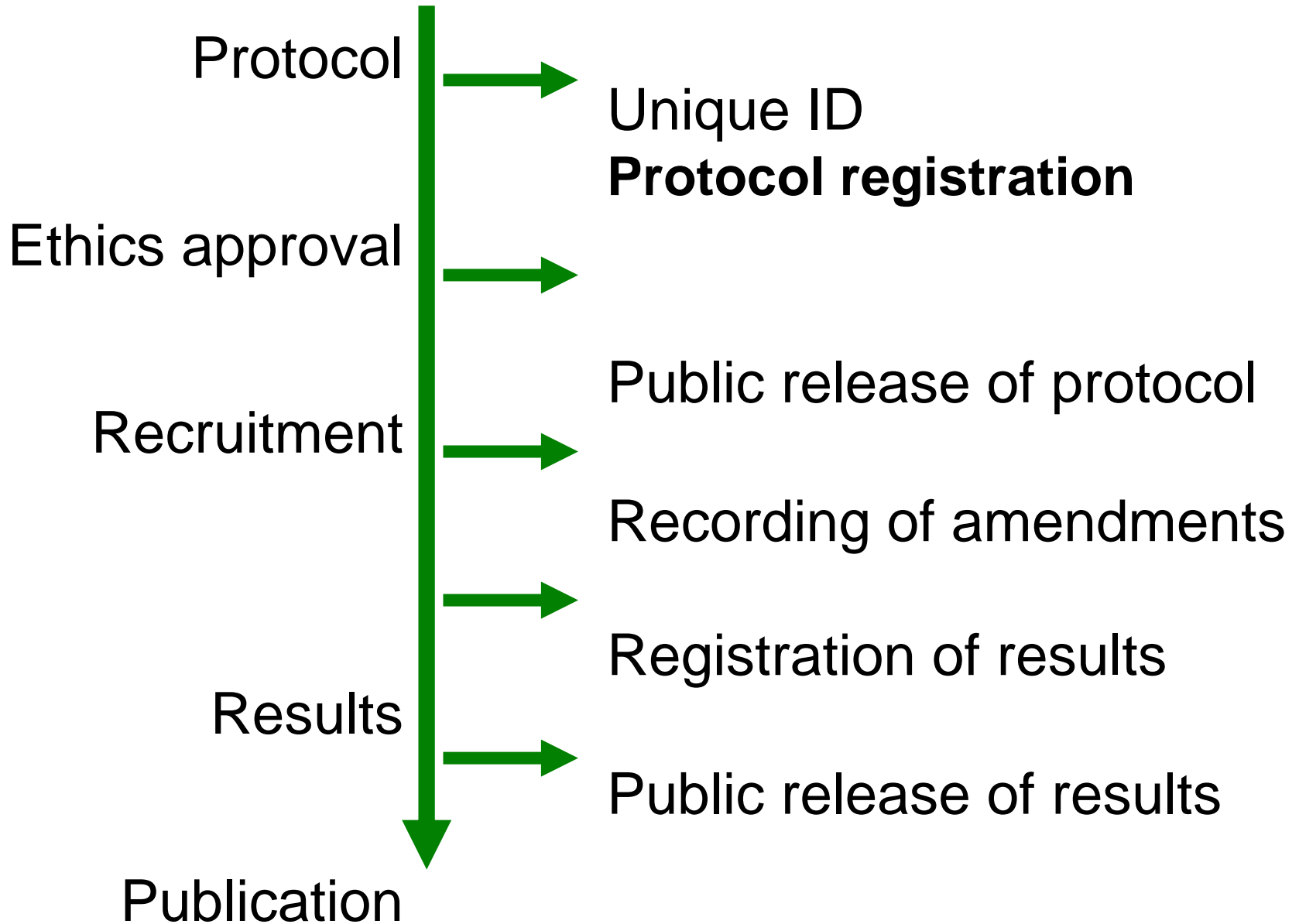
TIMING

Timing

Ottawa Statement 1, D.5.

- “Trial results should be registered once the analyses are completed and verified”
 - “Investigators should have sufficient time to publish their findings in a peer-reviewed electronic or print forum before the registered results are released for public, free-of-charge access. Timely public access to results should ultimately be assured regardless of their publication status. “
 - “If a trial is terminated prematurely, any available results should be registered along with the reason for termination”

Ottawa statement: general time-line for trial registration process



Timing of results reporting

COMPLETED TRIALS

Results **for each protocol-defined primary outcome** should be publicly disclosed as soon as possible and at the latest within 3 (2?) years of its protocol-defined assessment for the last recruited study participant.

Results **for all other protocol-defined outcomes** should be publicly disclosed as soon as possible and at the latest within 3 (2?) years from their assessment for the last recruited study participant.

Harms and other adverse events should be fully described and publicly disclosed as soon as scientifically/ethically possible.

Timing of results reporting

TRIALS STOPPED EARLY

Available results should be disclosed along with the reason for termination as soon as scientifically/ethically possible, and at the latest within a year of the trial stoppage date.

TIMING of Results Reporting – a Summary Table

Variable	Measurement time	Reporting time
Primary outcome	As defined in protocol for the last recruited study participant	3 (2?) years
Secondary outcome	As defined in protocol for the last recruited study participant	2 years
Harm/adverse events	as they occur	As soon as scientifically possible
Stopped early	Last assessment of the last recruited study participant	As soon as scientifically possible, at the latest within a year

Trial participants should be notified the public disclosure of results.

VENUE

Principles related to the **VENUE** for results disclosure

Form

- Internet-based repository for results
- No deletion of recorded information (i.e. all amendments are recorded)
- Independent validation is not required, but should be described if applicable
- Guarantor takes responsibility for the submitted data
- At least in English

Access

Open access (user identification by venue permissible)
Linked to register that meets WHO standards

CONTENT

KNOWLEDGE SHARING INITIATIVES

- Budapest Open Access Initiative, Feb 2002
 - Self-archiving;
 - Open access peer-reviewed journals
- Berlin Declaration on Open Access to Knowledge, October 2003
 - Individual patient data / raw data
 - Original scientific results
 - Metadata etc
- Ministerial Summit on Health Research, Mexico City, November 2004
 - Trial Registration
 - Systematic review

Ottawa Statement 1

D.5. Principles relating to registration of trial results

D.5.1. Definition of trial results to be registered

- At a minimum, results for outcomes and analyses specified in the protocol (as approved by the IRB/IEC), as well as data on harms, should be registered regardless of whether or not they are published. If a trial is terminated prematurely, any available results should be registered along with the reason for termination.
- The summary results recorded for each outcome should be sufficient for valid interpretation, and should not enable identification of any individual trial participant to the public.
- Full citations to trial publications should be registered as they become available. However, listing of study publications alone does not constitute adequate registration of results.

CONTENT

Two options are proposed. They should not be seen as either or, but in a sequence of their implementation:

- option one now
- option two in two or five years

This timeline enables gradual implementation and evaluation of each piloted step.

OPTION 1 - now

- Full initially-approved protocol and amendments
 - Trial consent form (for the primary site if >1)
- Statement about any independent validation
- **CONTENT:** combine CONSORT equivalent items with all elements of OS2 not included in CONSORT at this time
- List of publications
- *Note: No lay summary of findings (may facilitate industry marketing, press coverage etc)*

OPTION 2: operationalise in up to five years

- Option 1
- +
- Cleaned, anonymized (as per Health Insurance Portability & Accountability Act, EU standards), meaningfully-coded, individual participant-level, dataset
- Reference to systematic review(s)
 - Before trial start
 - After trial completed

Ottawa Statement 2 items to be registered

Unique ID

Key dates (anticipated)

Ethics approval

Coordinating center

Recruitment centers locations

Recruitment status (updated regularly)

Sources of monetary, material, personnel support

Sponsors

Objectives

Disease/Condition

Eligibility criteria

Interventions (details of dosage, contents etc)

Target sample size

Trial phase (I, II, III, IV, NA)

Controlled;

Design (parallel, crossover, etc)

Number of arms

Masking/blinding

Randomized

Allocation concealment

Framework (superiority, non-inferiority, equivalence, etc)

Primary outcome(s)

Secondary/additional outcomes

(including subgroup analyses and adverse events)

Lay summary of trial

Reference(s) to existing systematic review(s)

Attachments:

Consent forms

Full protocol

Analysis plan

Publication/disclosure agreements

Ottawa Statement 2 items to be registered

Clinical trial agreements/contracts

yes/no

if yes: with whom

publication or public disclosure of agreements (yes/no)

if yes, please specify or attach

Recruitment incentives

Ottawa Statement 3 items -- Results

- Actual key study dates (list them, update other fields (funding etc))

For each study group:

- Participant flow (numbers randomized, receiving intended intervention, completing protocol, analyzed for primary outcome, analyzed for secondary and other additional outcomes)
- Protocol amendments and dates
- Protocol violations (number and reasons)
- Dates of recruitment and follow-up- assessment
- Baseline demographic and clinical characteristics
- Analysis population (ITT, per-protocol etc)
- Numbers analyzed, size of effect and precision for each primary and secondary outcome (as defined in protocol)
- Subgroup analyses (pre-specified and exploratory)
- Adjusted analyses (pre-specified and exploratory)
- Harms and other adverse events

Based on CONSORT