



CLINICAL TRIALS AND COHORT STUDIES: TIPS, TOOLS & TEMPLATES

Michelle Dowsey BHealthSci, MEpi, PhD
NHMRC Career Development Fellow | Department of Surgery | University of Melbourne
Head Arthritis Research | Department of Orthopaedics | St Vincent's Hospital



Presentation Outline

- ▶ CTCS 2019
- ▶ Major Changes to the Grant Review Process
- ▶ Panel Structure/Composition
- ▶ Scoring Criteria
- ▶ Proposal Structure
- ▶ Tips, Tools & Templates



CTCS Grant Review Panels 2019

- ▶ 571 Applications
- ▶ COIs and SP Suitability end May for 155 applications
- ▶ Panels ran over 4 weeks August to September
- ▶ 2 panels per week
- ▶ Each panel reviewed ~ 25 applications
- ▶ Approximately two thirds NFFC



Major Changes to the Grant Review Process

Process	Pre 2019	2019
COI & SP Suitability	150-200	150-200
Panel numbers	12 to 16	8
SP lists provided	8 to 10 applications	8 to 20 applications
SP1	Score and write report	Score only
SP2	Score and write report	Score only
SP3	NA	Score only
External assessors	Write report	NA
Applicant	Rebut SP/Assessor Comments	No rebuttal
SP1 & SP2	Revise Scores	NA
NFFC generated	Lowest 50%	Lowest 65%
Rescue opportunity	1 application	1 application
Indicative panel List	3 weeks prior to panel	<1 week prior to panel



Panel Structure/Composition

- ▶ Chair (no deputy chair)
- ▶ Secretary
- ▶ 14 members
- ▶ Chair
 - ▶ Introduced app; removed conflicts; announced SP scores (2 mins)
- ▶ Spokespersons
 - ▶ 1SP summarised application (5 mins)
 - ▶ 2SP spoke about strengths & weaknesses (3 mins)
 - ▶ 3SP led panel discussion (5 mins)
- ▶ Rescoring of SPs and panel scores (3 mins)
- ▶ Budget discussion by exception if score >5 (5 mins)



Scoring Criteria

Category	Pre-2019	2019
Significance	25%	40%
Research Quality	50%	40%
Team Track Record	25%	20%

- ▶ Significance
 - ▶ No external assessor reports posed a challenge for scoring significance
 - ▶ Must be informed by exemplary analysis or review of existing studies
- ▶ Research Quality
 - ▶ Most robustly assessed by panel members
 - ▶ Flawless presentation/design
- ▶ Team Quality
 - ▶ Team must include clinicians
- ▶ Consumer Engagement
 - ▶ Must be meaningful



Proposal Requirements

- ▶ MUST HAVE:
- ▶ A well structured proposal set out per accepted guidelines
 - ▶ Consort guidelines, SPIRIT statement
- ▶ Systematic review evidence in support of application
- ▶ Pilot data
 - ▶ Publish if possible



Tips, Tools & Templates

- ▶ SEPTRE
- ▶ COVIDENCE
- ▶ BioMed Central



SEPTRE

- ▶ An innovative, web-based software solution that makes it easier to create, manage, and register high-quality protocols for clinical trials
 - ▶ Input protocol text
 - ▶ Generate formatted document
 - ▶ Upload into ClinicalTrials.gov
 - ▶ Free 30 day trial, individual and institutional subscriptions

SEPTRE

- 1** Input protocol text
- 2** Generate a formatted document
- 3** Upload seamlessly to ClinicalTrials.gov

01
EVIDENCE-BASED
PROTOCOL GUIDANCE

- Protocol content based the widely-endorsed SPIRIT standards
- Quick access to detailed SPIRIT guidance with model examples

SEPTRE
SPIRIT Evidence Protocol Text & Review

SEPTRE

- 1** Input protocol text
- 2** Generate a formatted document
- 3** Upload seamlessly to ClinicalTrials.gov

02
SEAMLESS UPLOAD TO
CLINICALTRIALS.GOV

Register your trial with the push of a button

The advertisement features a central laptop displaying the ClinicalTrials.gov PHS (Preclinical Submission and Review System) interface. The interface shows a 'Record Summary' for a trial, with a status of 'In Progress'. Below the status, there are sections for 'Record Owner', 'Last Update', 'Initial Release', 'Access List', 'Upload', 'PIR Review', 'Public Site', and 'FDA/ACT'. A 'Next Step' section indicates 'Final Protocol version' and 'Study Closure'. The 'Protocol Section' is also visible, listing 'Study Identification', 'Study Status', 'Sponsor/Co-sponsors', 'Change of', and 'Study Description'. A small '001' label is present in the bottom right corner of the laptop screen. To the left of the laptop, a large '02' is displayed with a plus sign above it and a green icon of a document with an upward arrow. Below the '02' is the text 'SEAMLESS UPLOAD TO CLINICALTRIALS.GOV'. The background is a light gray with a dark blue border at the top and bottom. A navigation bar at the bottom of the advertisement shows a series of dots, with the second dot from the left being filled, indicating the current step in the process.

SEPTRE

- 1** Input protocol text
- 2** Generate a formatted document
- 3** Upload seamlessly to ClinicalTrials.gov

+ 
04
SIMPLICITY



Trial design 

Description of trial design including type of trial (e.g., parallel group, crossover, factorial, framework (e.g., superiority, equivalence, noninferiority, exploratory).

FOR TRIAL REGISTRY AND SUMMARY

Study type:

Primary purpose:

Study phase:

Intervention model:

Number of arms:

Allocation:

MAIN PROTOCOL TEXT

- Input information using drop-down menus
- Content is auto-formatted and transferred to the trial summary and registry



SEPTRE

- 1** Input protocol text
- 2** Generate a formatted document
- 3** Upload seamlessly to ClinicalTrials.gov

06
PREVIEW

Sample trial
Protocol
Version draft - December 11, 2018

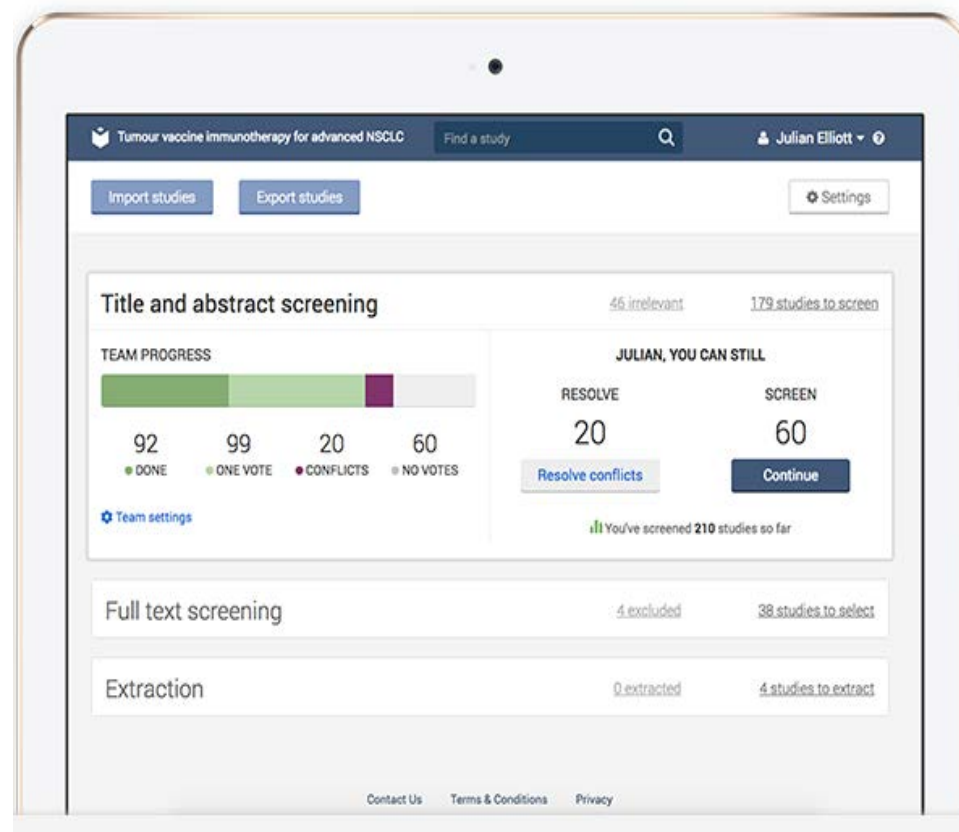
Study Principal Investigator: John Doe, MD, Sponsor test 1
Sponsor: Sponsor Name 1
Sponsor Name 2
Protocol contributors: Contributor 1
Trial identifiers:

Preview your work before generating an official version

SEPTRE
SPRINT Electronic Protocol Tool & Resource

COVIDENCE

- ▶ A component of Cochrane's review production toolkit
- ▶ A web-based systematic review management system
- ▶ Imports citations
- ▶ Screens titles and abstracts
- ▶ Uploads references
- ▶ Screen full text
- ▶ Create forms
- ▶ Populates risk of bias tables
- ▶ Extract data
- ▶ UoM has institutional subscription (free)
- ▶ <https://www.covidence.org/home>





BMC Pilot & Feasibility Studies

- ▶ Publishes research articles that are intended to directly influence future clinical trials or large scale observational studies, as well as protocols, commentaries and methodology articles
- ▶ Open access (cost \$2.9k)
 - ▶ UoM is a member of BMC (15% applies)
- ▶ PubMed
- ▶ Endorse peer review mentoring



Useful Links

- ▶ <https://www.spirit-statement.org/septre/>
- ▶ <https://www.covidence.org/home>
- ▶ https://www.youtube.com/channel/UCgr_cyJlrKYBjxjyMe2z9mw
- ▶ <https://support.covidence.org/help/are-you-a-new-covidence-user>

- ▶ <https://pilotfeasibilitystudies.biomedcentral.com/>
- ▶ <http://www.consort-statement.org/extensions/overview/pilotandfeasibility>
- ▶ <http://www.consort-statement.org/downloads/extensions>
- ▶ <http://unimelb.libguides.com/c.php?g=669501&p=5031785#s-lg-box-8392122>