Funding strategies for platform trials

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Australian Clinical Trials Alliance

www.clinicaltrialsalliance.org.au

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What is needed to run a platform

Moderately large amount of money....

REMAP-CAP common / central cost budget ~ 1.5M per year

- Global project manager, database, data coordination, statistical analysis
- Double national project management in each region


CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada


Strategy for Patient-Oriented Research
Stratégie de recherche axée sur le patient
SPOR SRAP
Putting Patients First
Le patient d'abord

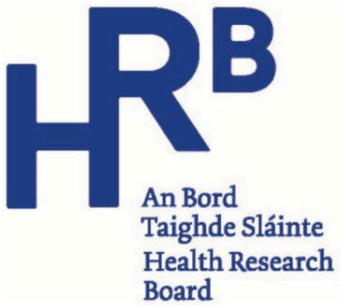

Platform foR European Preparedness Against (Re-)emerging Epidemics
PREPARE


SEVENTH FRAMEWORK PROGRAMME


hrc
Health Research Council of New Zealand


Australian Government
National Health and Medical Research Council


NHMRC


HRB
An Bord Taighde Sláinte
Health Research Board


NIHR | National Institute for Health Research


MINDEROO
FOUNDATION


BCRF
BREAST CANCER RESEARCH FOUNDATION

How REMAP-CAP got ~~lucky~~ funded

EU FP7 grant call for pandemic preparedness

- 24M Euro grant, around 2015
- Multiple work-packages
- WP5 was REMAP-CAP (two pages in a massive grant application)

On back of EU grant:

- NHMRC project grant
- HRC New Zealand program grant
- CIHR clinical trial grant

What contributed to successful NHMRC project grant

Already peer-reviewed and funded in Europe

Credibility of ANZICS CTG and investigator group

Sold the output, i.e. evidence generation and pandemic preparedness (not the design)

Explained the design.... 17 pages... progressively shortened story until it fit into 9 pages

Had some (very sketchy) simulations

Keeping the platform funded

Big investment in central infrastructure (like a registry)

Took REMAP-CAP 3 years to have more enrolments than investigators....

- Protocol development
- Database set up
- Site education

Funding during the pandemic

Didn’t need to go to funders in Australia

- Very generously supported by Minderoo Foundation (1 pager and 30 minute zoom call)
- Designated as priority study by CMOs in UK countries with NIHR support
- Additional funding in EU (15M Euro) and Canada

Post-pandemic

Proven track record / evidence of impact makes it easier

Australia 2 x MRFF grants (COVID with ASCOT, non-COVID ICTC)

Canada 2 x CIHR grants (separate COVID and flu grants)

UK NIHR funding (flu call)

NZ program grant submitted, with ASCOT

Horizon 2020 ECRAID in Europe (preceded pandemic)

What's needed to sell an adaptive platform trial

Credibility:

- Pre-existing clinical trial experience for investigator group (many trials, many patients randomised)
- Experienced clinical trial coordinating centre
- Experienced trial sites with access to sample size
- Don't have to have adaptive trials experience but need to show it can be developed
- Statistical expertise
- Suitable disease (first talk this morning)

International perspective

CIHR just announced trial results, at least 3 adaptive platform trials funded

NIH said to be moving heavily into platform trials

NIHR

- 200K / one year platform trial planning grants
- Commissioned grant for influenza platform

Australian perspective

At least 15 funded adaptive / adaptive platform trials from existing funding schemes

- MRFF ICTC, specific grant calls, clinician scheme
- NHMRC CTCS, CRE

ACTA Innovative Trial Design Working Group

Position of funding agencies (esp MRFF)

- Aware of design and its advantages (and challenges) and interested in developing ways APTs can be supported
- Want advice about prioritisation of diseases and conditions with emphasis on high public health impact
- Supportive of international collaboration
- Would like to see quantitative data on efficiency of design ('trial economics')

ACTA Innovative Trial Design Working Group

Challenges associated with funding APTs

- Need for simulations and design work prior to major funding submission
- Large quanta needed
- Larger central fixed costs
- Uncertainty about cost needed to reach conclusions (fixed costs over time and sample size)
- Uncertainty about number of domains (critical to efficient use of fixed central costs)
- Uncertainty about per patient payments if using a platform + domain model
- Capacity constraints for statistical (and operational) expertise

Innovative Trial Design Working Group: Proposals

Scheme to support simulations and design work (including consumer and end-user engagement) needed for major funding submission, like the NIHR 200K / one year grants

Scheme for establishment of new APTs

- competitive funding for core infrastructure and sufficient launch questions to justify the core infrastructure investment
- Possibly more iterative and with greater investigator-funder interaction (stop-go criteria)
- Mandatory involvement of Australian statisticians to build capacity

Scheme for recurrent funding

- New domains but with sufficient funding to cover core infrastructure
- Avoidance of mis-match between core infrastructure and domains

Innovative Trial Design Working Group: Proposals

Issues yet to be considered:

- Challenges of peer-review
- Pharma / industry involvement
- Shared infrastructure and expertise across multiple platforms

Discussion and questions....