MACH
Melbourne Academic Centre for Health
www.machaustralia.org

The National Clinical Trials Governance Framework

Project Completion Report
November 2022

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Acknowledgements

The Melbourne Academic Centre for Health (MACH) would like to acknowledge the Office of Health and Medical Research, DHHS for funding the Implementation of the National Clinical Trials Governance Framework (the "Framework') project.

MACH would also like to acknowledge the support by Murdoch Children's Research Institute (MCRI) for hosting the project team since commencement of the project in July 2019.

Background

The National Clinical Trials Governance Framework[1] (the "Framework") was developed by the Australian Commission on Safety and Quality in Health Care (the "Commission"). The Framework is applicable to Standard 1: Clinical Governance and Standard 2: Partnering with Consumers. All MACH partners who conduct clinical trials and come under the accreditation scheme, will be required to rapidly adapt and adhere to the standards in the Framework once it is implemented.

Due to the complexity of the Framework and the urgent requirement to comply, the MACH Clinical Trials committee allocated the MRFF funding provided to them to employ a Senior Project Officer for 12 months commencing July 2019 to this project. The VCCC has overlapping membership with the MACH and supported the project to assist health services implement the Framework.

An award from the Victorian Government received January 2020 enabled the MACH Clinical Trials Committee to support continuation of the Senior Project Officer role for a further 12 months from July 2020 until June 2021.

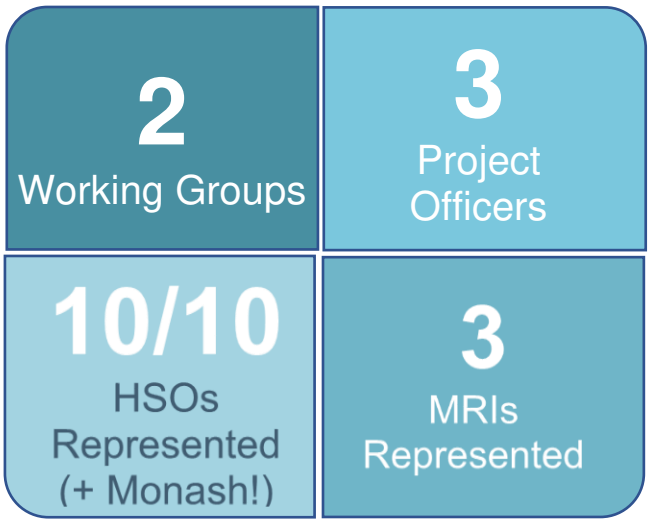
In June 2021, the Health Services participating in this project continued to fund a project officer through to November 2022.

[1] https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide

Project Quick Stats

Aims

- Prepare MACH sites for implementation of the NCTGF Standards 1 & 2
- Assist MACH sites to collaborate on Framework implementation projects
- Support MACH sites participating in the pilot & learn from them
- Streamline and co-ordinate best practice for common tasks
- Tackle challenges together



Working Group 1:

Standard 1 focussed
Clinical Governance Working Group
28 Members from 14 Organisations

Working Group 2:

Standard 2 focussed
Partnering with Consumers Working Group
25 Members from 13 Organisations
Plus our consumer representative

Membership Institutions:

RCH, MCRI, RMH, Austin, Eye and Ear, CERA, Peter Mac, Northern, VCCC, Mercy, SVHM, Monash, Western, RWH

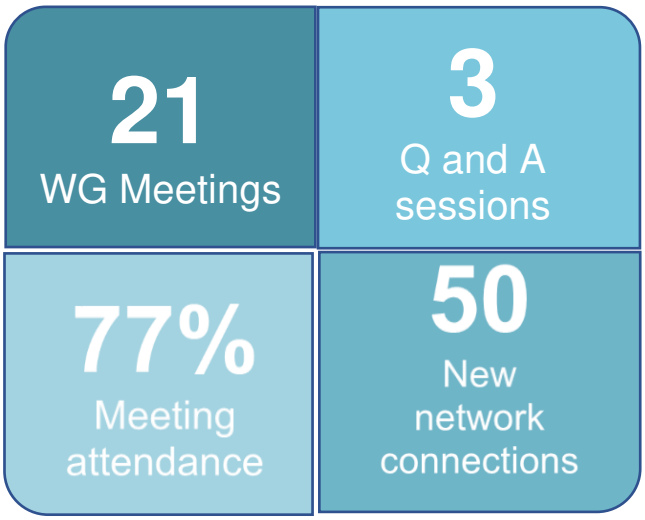
Meetings

9 meetings per working group, occurring bi-monthly between September 2020 and November 2022

3 Combined Meetings (where both working groups attended together) - June 2021, December 2021, November 2022

Q and A Sessions

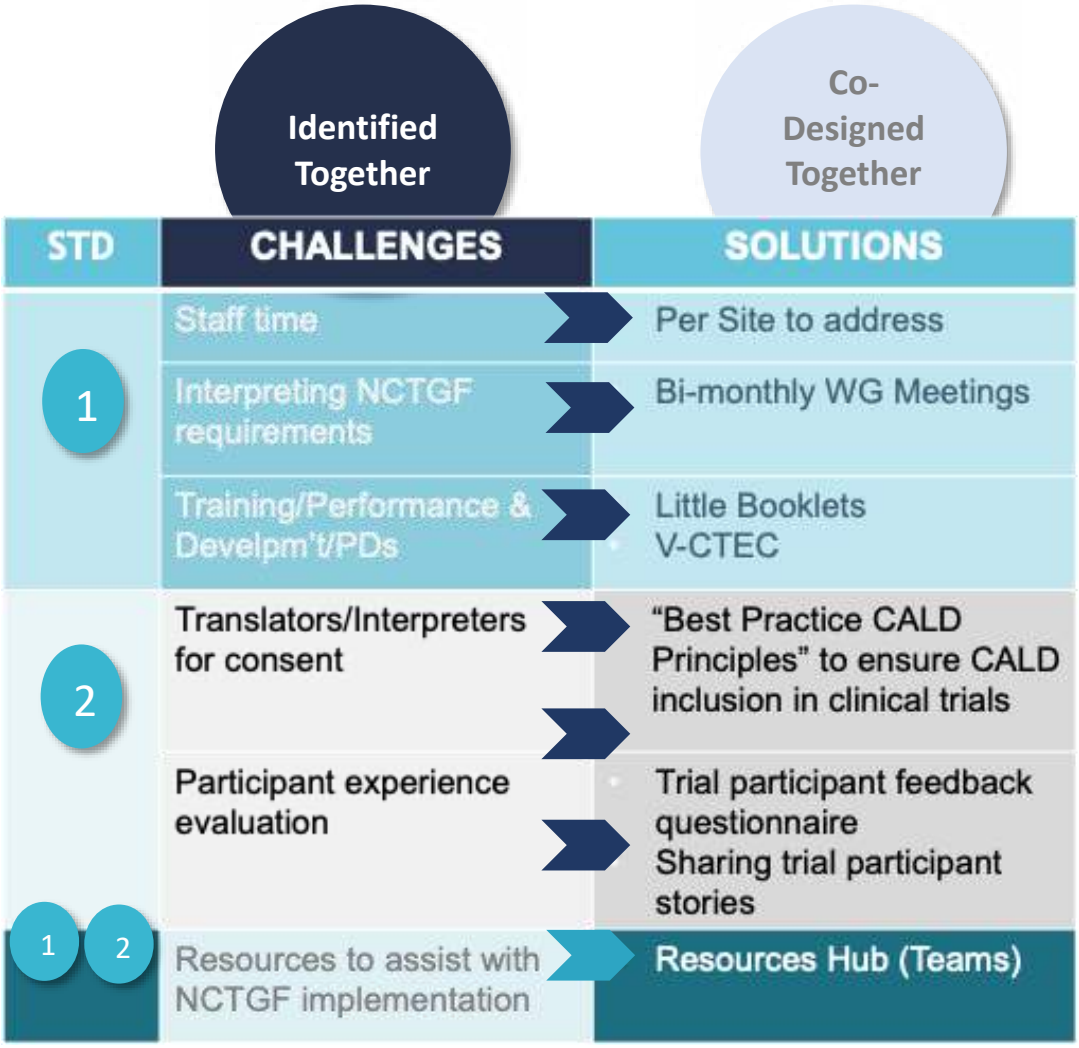
2x Pilot Information Sessions (one from Eye & Ear and one from St Vincent's Melbourne, both pilot sites)
1x session with Bernadette Aliprandi-Costa *(Manager, Safety & Quality Improvement Systems & Inter-governmental Relations, Australian Commission on Safety & Quality in Health Care)* and Fiona Loughlan *(CEO, Institute of Healthy Communities Australia)*



Other:

Attendance at ARCS in 2022 meant the members of this project were one of the firs to hear about the May 2022 delay of the framework, when its implementation was pushed back to January 2023. This information was a priority for our members, as some of them were scheduled for accreditation in July and August 2022.

Project Accomplishments



Standard 1

Staff Time/Interpreting NCTGF Requirements

The bi-monthly working group meetings have been the key strategy to "solve" the staff time and interpretation challenges identified by members. The working groups are cross-disciplinary, including representatives from quality, research, and partnering with consumers departments. The diversity of perspectives offered by this has been key to easing concerns and reducing burdens.

Training/Performance & Development/PDs

Originally the intent was for this group to develop standardised/universally accepted competencies and accountabilities for various position descriptions involved in clinical trials. The competencies work was absorbed by V-CTEC, and the accountabilities are in the little booklets.

The little booklets ("Clinical Governance and You" for Standard 1 and "Partnering with Consumers" and you for Standard 2) are resources staff can use to assess themselves against their framework accountabilities under the framework, because they contains a list of their accountabilities (by workforce position), a set of reflective questions for each accountability and who else shares that accountability.

Standard 2

Translators/Interpreters for Consent

Hospitals need procedures to improve interactions with CALD service users, so that they can be

confident the participants really do understand the information that has been provided to them. The working group co-designed best practice principles for interacting with CALD service users. These principles are service-level, at the same level at the framework, and designed to be achievable using the resources HSOs currently have.

They also underwent significant consumer review from our own consumer, Jo Cockwill, as well as Prof Stephanie Brown (MCRI), her community researchers (who live and work in the CALD communities they come from) and Prof John Hajek (UoM).

Participant experience evaluation

The framework requires HSO partner with service users to improve the quality of clinical trial service provision. In collaboration with the VCCC P-PEX Project, and using the Transcelerate questions as a starting point, a set of trial participant feedback questions was co-designed and developed by the working group. The questions are implementation-naïve, so they can be implemented in any form at any HSO, no matter their pre-existing questionnaire infrastructure.