

CIF Strategic Objectives

(formed as part of the RDTF's Strategic Objectives)

Strategic objectives

1. Being a trusted partner,
2. National Clinical Trials Harmonisation.

Key areas of activity

1. Being a trusted partner:
The RDTF is considered by health sector stakeholders (including government) as a credible body that effectively represents industry's views – this work has been supported by CIF members who are representatives on the RDTF.
 - ✓ Industry award at ACTA 'Trial of the Year' awards event
 - ✓ Representation by RDTF Sponsor representatives, including MTAA CIF members, at conferences and industry related meetings
 - RDTF will develop a calendar of events at which the RDTF could be represented (including by setting up stalls)
 - representatives expected to provide feedback on their attendance.
 - ✓ Ensure RDTF is well publicised (MA and MTAA can assist with communications-related work)
 - the CIF must ensure the MTAA CT webpage is kept up to date
 - ✓ Provide feedback and advice on clinical trials-related projects proposed by other organisations (for example, to enhance their efficacy and suggest alignment with harmonisation to ensure that project outputs/outcomes have national application)
 - this type of work could generally be done by RDTF members outside of RDTF meetings
 - for example, the skills gap analysis collaboration between MTP Connect, MTAA, AusBiotech, ANDHealth and MA.
 - ✓ Identify and address issues specific to the clinical trials sector as they arise
 - for example, issues could be addressed by timely Sponsor/member advocacy to government.

Output/Outcome

- Stakeholders approach RDTF and CIF for advice, support and collaboration.
2. Advocate for, advise and support efforts on National Clinical Trials Harmonisation – MTAA representatives on the RDTF would act as a channel, feeding information back and forth from the RDTF and the CIF – examples include:
 - ✓ Aust. Commission national standards/accreditation work (Helen A of the RDTF works directly with and supports the Commission)

- ✓ Advise Fed Govt on national initiatives such as the “Front Door” and the “One-stop shop”
- ✓ Seek advice from (or propose to) Govt how the RDTF and CIF can assist with other harmonisation and clinical trial efforts, including by identify gaps in national policy and sectoral capacity
- ✓ Feed into work on opportunity costs of Aust missing out on clinical trials

Output/Outcome

- RDTF supports the industry policy efforts that deliver national harmonisation outcomes in accordance with set milestones, including advising the Federal Government on how the Front Door concept should be fit for purpose for industry (MTAA CIF members of the RDTF MUST represent a more prominent presence in relation to this).

Corporate Governance in addition to the CIF’s TORs

- ✓ CIF meetings will run for approximately 2 hours, unless an agreed agenda requires otherwise.
- ✓ CIF agenda to mirror strategic priorities and project plan:
 - project plan to be updated during/after each meeting to monitor progress and members’ input
 - all members expected to contribute to CIF and RDTF work.
- ✓ The CIF Chair or a selected CIF representative must be present at each IPC meeting to provide an update of the progress of the CIF
- ✓ The below points relate to the CIF and RDTF Meeting Minutes and public communique on outcomes/advice/actions:
 - communiques disseminated as part of the RDTF will be published on MTAA’s public websites (at a minimum – approved communiques could be used by RDTF members);
 - minutes of RDTF meetings will be published on ‘Members’ Only Area’ of MTAA’s website;
 - high level project plan to be published on ‘Members’ Only Area’ of MTAA’s website;
 - detailed project plan to be overseen by RDTF Co-Chairs with support from the three Sponsors (MTAA, MA and AusBiotech);
 - shared IT storage platform to be used for RDTF documents (possibly use existing MTAA platform).