Cancer Research UK
New Agents Committee

Terms of Reference

This document sets out the key responsibilities that the **Scientific Executive Board** (**SEB**) has delegated to the **New Agents Committee** (**NAC** or the **Committee**).

1. Remit

1.1 To review and prioritise, novel anti-cancer agents from prospective industrial and academic collaborators for preclinical development and testing in early clinical trials in the UK, sponsored by Cancer Research UK (**CRUK**) and managed by the Centre for Drug Development (**CDD**), or sponsored and managed by other reputable organisations, to ensure that CRUK remains an international leader in the field of cancer drug development and early clinical trials in cancer.

Novel agents can include small molecules, biologically manufactured agents and human cells for use as preventives, diagnostics and therapeutics, and can include novel combinations of treatments.

1.2 In fulfilling their remit the NAC will work with:

- CDD
- Advisory groups established to assist the NAC.
- The Protocol Safety and Review Board (**PSRB**), for scientific and ethical review of CDD's Phase I and II clinical trial protocols.
- Cancer Research Horizon's Clinical Partnerships Team.
- The Experimental Cancer Medicines Centres (**ECMCs**) and the wider CRUK-funded network of preclinical and translational scientists to collaboratively build a national portfolio of high quality, hypothesis-testing early phase clinical trials in cancer.

2. Terms of Reference

2.1 Provide peer review of the highest international standards in the assessment of drug development studies, ensuring the maintenance of an internationally competitive portfolio.

2.2 The Committee will comply with the CRUK Code of Practice for Committees and Panels, which includes declaring conflicts of interest and maintaining confidentiality.

2.3 The Committee will specifically review proposals for drug development studies to assess:

- The novelty of the proposed target and/or anti-cancer agent.
- The scientific rationale for the target and the adequacy of the supporting preclinical data package.
- The 'deliverability' of the project.
- Clinical direction and the unmet medical need that will be addressed by development of the proposed candidate.

2.4 Score and prioritise, on the basis of scientific novelty, rationale and clinical need, those novel agents that are worthy of testing in humans.

2.4 To consider comments from any prior reviewing panel, external reviewers and advisory

groups, and to provide clear recommendations on the potential clinical value and the appropriate development pathway for the novel agent.

2.5 To recommend projects to be taken into the CDD Portfolio and commitment of CDD resources required to undertake them. Selection of projects by CDD will be based on the external review comments, scientific score, prioritisation and resources available.

2.5 To provide expert advice on opportunities for CRUK and the ECMCs to position the UK as an internationally competitive force in cancer therapeutics.

2.6 Ensure the maintenance of an internationally competitive research portfolio, which is targeted to the fulfilment of Cancer Research UK's mission, by recommending resources on the basis of scientific excellence and relevance to Cancer Research UK's research strategy.

2.7 When requested:

- Review and approve exploratory and preclinical development work and additional resources for approved projects.
- Provide advice and expertise in order to improve the quality of the clinical protocol design.
- Review the conduct of ongoing CDD studies.
- Review relevant data on the conduct of a specific clinical trial, advise on issues that arise, and recommend early suspension or closure of a trial if appropriate.

3. Membership

3.1 The Chair will be agreed by the SEB. The Chair will serve for an initial term of three years, renewable for a further 3 years. The Chair and Vice Chair will be from different institutions.

3.2 NAC members:

- Will be approved by the CDD Leadership Team and notified to SEB as part of an annual update.
- Will serve for an initial term of three years, renewable for a further 3 years.
- Must be off NAC for a minimum of three years before they are eligible to return as a member.
- Less than 50% should be Lead Investigators on NAC approved DD Projects.
- Should reflect diversity across protected characteristics as defined under the Equality Act 2010 as amended.
- Women should ideally comprise 50% of the membership. Individuals from ethnic minority backgrounds should ideally comprise 20% of the membership. The gender and ethnic balance of NAC must be reported annually to SEB along with data regarding other protected characteristics, where available.
- 10-20% of membership should comprise industry representatives, members from overseas or other independents in order to add diversity of knowledge and experience.
- No more than 20% should be from the same institution.
- In general, members should not serve on more than one other CRUK committee or panel simultaneously.

3.3 Membership will comprise non-clinical and clinical experts, including some representatives with appropriate expertise from the ECMCs, to ensure that, where possible, the expertise listed below is provided:

- **Scientific:** Drug discovery, translational development, immunology, pharmacology, chemistry, toxicology, molecular biology, virology, assay development, biomarkers.
- **Pharmaceutical:** Pharmaceutical sciences, formulation, biologics production, process development, cell production, industry experience.
- **Clinical:** Medical and immuno-oncology, immunotherapy, early clinical trials, small molecule and biological therapies, cell therapy, vaccines, antibodies, gene/viral therapy, children's cancer, clinical oncology, functional imaging, specific tumour types.

3.4 Where a lack of expertise has been identified, CDD may co-opt experts on an ad hoc, time limited basis where appropriate.

4. Meetings

4.1. In general, the NAC meets up to four times a year.

4.2. CDD will operate mechanisms for recording members' conflicts of interest and for dealing with conflicts of interest during the conduct of committee business.

4.3. CDD will provide an annual update to the SEB on NAC and the CDD Portfolio and discuss new strategic opportunities and/or challenges relating to the development of the portfolio.

5. Review

5.1 These Terms of Reference will be reviewed as needed and at least once every two years.

6. Document information:

Version	9
Approved by	Scientific Executive Board
Last approved	December 2023
Next scheduled review	December 2025
Document owner	Research Funding Manager (Drug Development)
Schedule of amendments	Revisions to update current NAC practice, reporting to SEB, membership requirements & working with CRH