Cancer Research UK
New Agents Committee, Exploratory Research Panel & Translational Research Panel

Supplementary 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**) and its panels, the Exploratory Research Panel (**ExRP**) and the Translational Research Panel (**TRP**). It should be read in conjunction with the General Terms of Reference for Funding Committees.

1. Remit

1.1 To review, prioritise, and fund novel anti-cancer agents 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 remits the NAC and its panels will work with:

- The CDD, for project and clinical study management, clinical data collection, entry and analysis, pharmacovigilance, quality assurance, production of final reports and other legal and contractual obligations arising out of its activities.
- Advisory groups established to assist the NAC and its panels.
- The Protocol Safety and Review Board (**PSRB**), for scientific and ethical review of CDD's Phase I and II clinical trial protocols.
- Clinical Development Partnerships (**CDP**), the CRUK initiative to bring shelved industry drugs and biotech assets to the clinic through the CDD.
- 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.
- Radiotherapy-Drug Combinations Consortium (RaDCom) a joint initiative between CDD and the Clinical and Translational Radiotherapy Research Working Group (CTRad) to develop and deliver preclinical projects evaluating radiotherapy-drug combinations, to provide supporting data for early phase clinical trials.
- The ECMC Combinations Alliance, an initiative by CDD to bring studies of novel combinations of industry agents to the clinic.

2. Additional Terms

2.1 ExRP will specifically review proposals for exploratory 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 viability of the manufacturing strategy and 'deliverability' of the project
- Clinical direction and the unmet medical need that will be addressed by development of the proposed candidate.

2.2 TRP will specifically review proposals for clinical drug development studies to assess:

- Project viability for both translation to the clinic and achieving its endpoints
- The quality and feasibility of the clinical trial concept including the proposed translational research aspects, pharmacokinetic, pharmacodynamics, immunological, biological and functional imaging endpoints
- The continued novelty of the proposed target and/or anti-cancer agent
- The adequacy of any additional preclinical efficacy and initial safety data
- Progress of manufacturing development studies.

2.3 To take into account any comments from prior reviewing panel, external reviewers, and any advisory groups, and to provide clear recommendations on the potential clinical value and the appropriate development pathway for the novel agent.

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

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

2.6 To review and approve exploratory and preclinical development work and, when required, review and approve additional resources and funding for approved projects.

2.7 When requested, to review the conduct of ongoing CDD studies.

2.8 When requested, to 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.

2.9 To provide advice and expertise in order to improve the quality of the clinical protocol design as required.

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

3. Membership

3.1 The Committee and panels will comply with the membership requirements set out in the General Terms of Reference for Funding Committees.

3.2 The NAC Chair and NAC Vice Chair will also be Chair and Vice Chair of the TRP and should be from different centres.

3.3 The ExRP will have two Chairs, each from a different centre.

3.4 Members of the ExRP and TRP will also be members of the NAC.

3.5 Membership will comprise manufacturing, 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 and development, immunology, pharmacology, chemistry, toxicology, molecular biology, viruses, viral delivery, angiogenesis, assay development, biomarkers.
- **Pharmaceutical:** Pharmaceutical sciences, formulation, biologics production, process development, cell production, industry experience.
- **Clinical:** Medical oncology, immuno-oncology, clinical oncology, children's cancer, early clinical trials, small molecule therapies, biological therapies, cell therapy, vaccines, antibody targeted therapy, gene/viral therapy, endocrine therapy, radioimmunotherapy, functional imaging, specific tumour types.

4. Meetings

4.1. In general, the NAC meets once a year, the TRP up to three times a year, and the ExRP up to six times a year.

4.2. If invited by the SEB, the Chair of the Committee will attend an SEB meeting on an annual basis to ensure that the Committee is aligned with the strategic priorities of Cancer Research UK.

5. Document information:

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