

## New Agents Committee (NAC)

### Supplementary Terms of Reference

- 1 Remit:** The NAC is a sub-committee of the Clinical Translational Research Committee with a remit to review, prioritise, select and fund novel anti-cancer agents for development and testing in early clinical trials, Sponsored by Cancer Research UK (CR-UK) and under the management of the Drug Development Office (DDO), and to ensure that CR-UK remains an international leader in the field of cancer drug development and early clinical trials in cancer. Novel agents can include small molecules and biologicals for use as preventives, diagnostics and therapeutics. Proposals can include combinations of agents.

If resources permit, to review, prioritise, select and fund the best novel anti-cancer agents for development and testing in early phase clinical trials in the UK Sponsored and managed by reputable UK organisations other than CR-UK.

In fulfilling its remit the NAC will work with:

- (i) The DDO, 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.
- (ii) Advisory groups established to assist the NAC, e.g. the Pharmacokinetic and Pharmacodynamic Technologies Advisory Committee (PTAC); for expert advice on opportunities to integrate high quality translational research endpoints into the clinical protocol.
- (iii) The Central Institutional Review Board (CIRB), for scientific and ethical review of the Phase I and II clinical trial protocols.
- (iv) Clinical Development Partnerships (CDP), the joint initiative between CR-UK and CRT to bring shelved industry drugs to the clinic through the DDO.
- (v) The Experimental Cancer Medicine Centres (ECMC), to work together to build a national portfolio of high quality, hypothesis-testing early phase clinical trials in cancer.

## 2 Additional Terms:

2.1 To 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 for taking a new therapeutic against this target into man
- the adequacy of the preclinical data package to support clinical development
- the quality and feasibility of the clinical research proposal
- the translational research aspects of the proposal, e.g. pharmacokinetic, pharmacodynamic, immunological, biological and functional imaging endpoints.

- 2.2 To take into account the comments from external reviewers and any advisory groups, such as PTAC, and provide clear recommendations on the potential clinical value and the appropriate developmental pathway for the agent.
- 2.3 To score and prioritise, on the basis of scientific novelty, rationale and clinical need, those new treatments that are worthy of testing in man.
- 2.4 To select projects to be carried out and allocate the funding and resources required to undertake them. Selection of projects will be based on the scientific score, prioritisation and the resources available.
- 2.5 To review and approve exploratory and preclinical developmental work and, when required, review and approve additional resources and funding for approved projects (grants, etc).
- 2.6 To routinely review the conduct of all ongoing DDO studies.
- 2.7 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.
- 2.8 To ratify the selection of CR-UK clinical centres for undertaking early phase clinical trials.
- 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 CR-UK and the ECMCs to position the UK as an internationally competitive force in cancer therapeutics.

### **3 Membership:**

The membership will comprise clinical representatives with appropriate expertise from some of the Experimental Cancer Medicine Centres and other individuals to ensure that the expertise listed below is provided:

- Clinical: Medical oncology, clinical oncology, early clinical trials, small molecule therapy, biological therapy, gene/viral therapy, cell therapy, vaccines, antibody targeted therapy, endocrine therapy, children's cancer, radioimmunotherapy.
- Scientific: Drug discovery/development, pharmacology, chemistry, immunology, toxicology, molecular biology, viruses, viral delivery, angiogenesis.
- Pharmaceutical: Pharmaceutical sciences, formulation, biologicals production, cell production, radiolabelling, industry experience.
- Functional Imaging: NMR, gamma camera/ SPECT, PET.

### **4 Meetings:** the NAC will meet four times a year.