2026

C3PT TOOL

Operational Considerations

for Academic-Industry Collaborative Platform Trials in Paediatric Oncology

v 1.0

MRCT CENTER
THE MULTI-REGIONAL CLINICAL TRIALS CENTER OF BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD

ITCC
INNOVATIVE THERAPIES FOR CHILDREN AND ADOLESCENTS WITH CANCER

Blood Cancer United

CHILDREN'S ONCOLOGY GROUP

Purpose and Scope of Tool

The design and conduct of an academic-industry collaborative trial is a complex and resource intensive undertaking, requiring diverse skills and facilities. This tool identifies the principal operational considerations and expertise needed to be able to successfully sponsor and deliver this type of trial and where the distribution of responsibilities need to be agreed between academic and industry partners at the outset.

This operational considerations checklist specifies the necessary expertise and delineation of responsibilities to be agreed upon between academic and industry partners at the outset.

Introduction

In the context of an academic-led platform trial conducted in collaboration with industry partners, this checklist is a tool intended to be used by the academic sponsor. It is intended to prompt the sponsor to consider whether they have access to the expertise and capabilities necessary for effective conduct of their academic-industry collaborative platform trial. If not, they should consider the additional planning and preparation that will be needed, including whether they need to outsource certain capabilities to the industry partner or other third party.

As the academic sponsor of the platform trial, determine if you have access to the following expertise and capabilities necessary for effective conduct of your academic-industry collaborative platform trial. If not, additional planning and preparation will be needed.

Paediatric and/or Disease Area Expertise Relevant to the Trial	
Have you identified your Lead investigator(s)?	○ Yes ☐ No
Have you identified your patient advocate(s)?	○ Yes ☐ No
Do your investigators and patient advocates have the expertise and capabilities to:	
Formulate key questions to be addressed in the trial?	○ Yes ☐ No
Evaluate and prioritize therapies to be studied?	○ Yes ☐ No

Governance and Oversight (steering/leadership team)	
Have you convened a leadership team (i.e., Trial Steering Committee) with the relevant breadth of skill sets and expertise to have oversight of your platform trial?	○ Yes ☐ No
Does your leadership team have access to entities such as industry partners, health institute portfolios or other sources that can provide assets and input regarding asset development?	○ Yes ☐ No
Do you need additional expert clinical input from surgical and/or radiation specialists or other healthcare professional relevant to your platform (depending on trial type)?	○ Yes ☐ No
Have you identified nursing, pharmacy and other relevant professionals who can provide input?	○ Yes ☐ No

Operational Team

Does your platform trial's operational team include/require the following capabilities and capacity:	
Adequate project manager(s) and /or trial manager(s)?	○ Yes ☐ No
Ability to create and manage study related documents (protocol, consents, amendments, safety memos, lab manual, pharmacy manual, data monitoring plan, statistical analysis plan)?	○ Yes ☐ No
Trial implementation capabilities:	
Site feasibility and qualification assessments	○ Yes ☐ No
Site training	○ Yes ☐ No
Government and public-facing document and website information management (clinicaltrials.gov, EU Clinical Trials Register, etc)	○ Yes ☐ No
Central laboratory selection; other vendor selection	○ Yes ☐ No
Access to legal and contracting personnel	○ Yes ☐ No
Budget and coverage analysis personnel	○ Yes ☐ No
Pharmacovigilance and safety reporting capacity	○ Yes ☐ No
External Data Safety Monitoring Board	○ Yes ☐ No
Quality Management System and oversight	○ Yes ☐ No
Internal /organizational auditing processes	○ Yes ☐ No
Confidentiality and conflict of interest oversight processes	○ Yes ☐ No

Financial Support	
Have you secured funding for core resources to develop and sustain the trial platform's operational team?	○ Yes ☐ No
Does your funding model support sites in their conduct of the trial?	○ Yes ☐ No

Regulatory Aspects of Sponsorship	
Do you have the experience and expertise to act as a sponsor of an academic trial?	○ Yes ☐ No
For USA based trials, do you have the experience and expertise to interact with regulatory authorities (FDA/EMA) and to hold the IND (US)?	○ Yes ☐ No
For European based trials, do you have the experience and expertise to manage interactions with Competent Authorities in Europe (in the EU via the Clinical Trials Information System (CTIS) and Research Ethics Committees)?	○ Yes ☐ No
Do you have the experience and expertise to manage the trial's pharmacovigilance safety requirements?	○ Yes ☐ No

Regulatory Compliance Expertise	
Do you have, or have access to, expertise in conducting trials that will contribute to a PIP or iPSP and/or a marketing authorization application?	○ Yes ☐ No

Biostatistical Expertise	
Does your biostatistics and trial methodology team have experience in designing and implementing platform and adaptive trials?	○ Yes ☐ No

Data Management Capability, Informatics Support, Case Report Form Expertise	
Do you have the expertise and capacity to develop the required databases, case report forms and data management oversight to deliver the platform trial?	○ Yes ☐ No

Operational considerations that may ***be the responsibility*** of the academic sponsor of the platform trial OR shared with the industry collaborating partner	
Might any of the following trial responsibilities be delegated or shared with the industry collaborating partner or a third-party vendor:	
Biostatistical support	○ Yes ☐ No
Correlative studies, biomarker evaluation, pharmacokinetics	○ Yes ☐ No
Trial site monitoring	○ Yes ☐ No
Drug distribution and labelling	○ Yes ☐ No
Central review of response assessment capability	○ Yes ☐ No