2026

C3PT TOOL

Evidence-Based Consolidated Independent Expert Opinion (EBCO)

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

This tool describes the suggested multi-stakeholder composition of an expert board to be established to provide authoritative advice about the inclusion of assets in the proposed platform. The EBCO board should assist the Industry partners in their development pathway for an asset. The independence of the panel experts providing a consolidated opinion ensures industry partners can use the EBCO opinion with confidence, and will help to shape their approach to compliance with regulatory obligations.

Introduction

A committee that is able to provide evidence-based consolidated independent expert opinions on paediatric oncology drug development (EBCO) should be established to provide authoritative advice about the inclusion of medicinal products in the platform trial and support the development pathway for the asset.

Regulatory endorsement of the platform trial would further encourage industry partners to engage with the EBCO with confidence. In turn, the EBCO's determinations can help the industry align its development plans with regulatory obligations.

Suggested EBCO Composition

To effectively carry out its remit, the EBCO must have a constitution that includes recognised international disease experts from the whole geography represented by the trial (and outside of the trial where it is not 'global'). Experts should be active leaders/members of major disease relevant international study groups/consortia. To ensure transparency and independence of the EBCO, a declaration of interests policy must be in place (The **ANNEX** provides an example adapted from Glo-BNHL trial) with a managed register available for review on request.

- Independent Chair
- Chief Investigator
- Statistician(s)—including at least one independent
- Academic Clinicians: treatment arm leads
- Academic Clinicians; globally representatives
- Consumer Representatives; globally representative
- Sponsor representative
- Trial Management representative(s)

The EBCO's remit

The EBCO will appraise the 'drug information pack' submitted by the potential industry partner in a timely manner. A timetable should be published to inform industry of the EBCO review cycle. An example is available on the Glo-BNHL website: [https://www.birmingham.ac.uk/research/crctu/trials/glo-bnhl/professionals/apply-to-collaborate-with-glo-bnhl]].

The review should evaluate the information in the 'drug information pack' with aim of determining if the asset should be prioritised for inclusion in the platform trial. The EBCO should take into consideration:

- The scientific merit of the medicinal product
- The strength of evidence of activity in the platform's indication (paediatric and adult data where relevant)
- The feasibility of delivery in a paediatric population
- The mechanism of action of the medicinal product

The EBCO will produce a report detailing the decision and rationale regarding whether to prioritise the asset for inclusion in the trial. The statement should be returned to the potential pharmaceutical partner within a pre-defined period (as per example above) of the full drug information pack being received.

Additional Guidance for the EBCO Board

- A quorum for the EBCO should be established and all meeting minutes should be made available to the potential collaborator upon request.
- The platform should develop materials to guide the completion of the 'drug information pack' to be reviewed (examples: ***Glo-BNHL Industry Information Pack »*** and ***Glo-BNHL Asset Submission Form »***).
- Assets should be reviewed using a standardised methodology available for review upon request. For an example of a scoring matrix for prioritisation of assets, see: Seaford, E., et al (2023). Blood, 142(Suppl 1), 6247. https://doi.org/10.1182/blood-2023-178724
- Upon completion of the asset review, a formal report should be produced and copied to the relevant regulatory body. i.e., EMA and/or FDA, as agreed in the confidential disclosure agreement (CDA) supporting the asset review.

ANNEX

Guidance For Managing Competing Interests And Objectivity: Participation In An Evidence-Based Consolidated Expert Independent Opinion Committee (EBCO)

The purpose of identifying and mitigating potential conflicts of interest is to ensure the integrity of the decision-making by the platform and of the trial conduct. The European Medicine Agency (EMA) has charged the platform EBCO with prioritisation of assets for inclusion. As such, any appearance of conflict, or of being in a position to possess or share proprietary information compromises the conduct of platform.

At the opening of each EBCO meeting, prior to discussion of any substantive items, each EBCO member must declare whether any potential conflicts have arisen in any of the categories listed below since the previous meeting. Platform participation activities must be declared and updated if the EBCO member's role changes or their participation changes.

Involvement in development of an asset that has been prioritised by the EBCO for inclusion in platform as a competing study would constitute a conflict in interest and recusal from some platform activity would be expected. It is anticipated that platform members would not take leading roles in developing a separate competing trial outside the platform organisation. If an asset is not prioritised by the platform, then the PI of any resulting competing trial should not be excluded from platform participation, but that member's involvement should still be declared, and should there be changes in the future, new risk/conflict mitigation should be discussed at the earliest possible opportunity before inclusion in a subsequent EBCO. Below are examples of interests that might compete. Depending on the nature of the interest, this will not necessarily exclude you from membership.

TABLE : Four main categories of trial participation activities which present a potential/potentially perceived Conflict of Interest

Trial Participation Activity	Is this a Conflict of Interest?
1. Participation in **Advisory Boards** and/or Consultant role in meetings or planning groups, regardless of number of meetings, duration of involvement, or if service is paid or unpaid. For clarity; individuals are giving expert advice to a company on an asset or pipeline of assets but their involvement in the asset(s) further development does not extend beyond the defined advisory board or consultancy meeting.	**Yes** The degree/level and type of involvement, duration of service, and status of remuneration should be disclosed and updated with any EBCO member's changes.
2. Participation as a site **Investigator/ co-Investigator** in competing industry which enrols the same patient population while an active platform arm is available or academic trials. '**Investigator**' is defined as a participating treating professional without having decision-making capacity regarding protocol response judgements, study design, data analysis role.	**No** Not privy to confidential details such as data review and analysis, toxicity, or response determinations, or trial decision-making other than providing details about individual patients treated personally at their institution.

Trial Participation Activity	Is this a Conflict of Interest?
3. Participation in competing industry-sponsored trials as **Chief Investigator (CI), Contact Investigator, national or international Principal Investigator (PI)** with formal contractual agreements (personal or institutional) with companies to develop a competing product.	**Yes** Privy to confidential details of other trial(s), response and toxicity data that are not in the public domain, and similar proprietary information that could "cloud" neutrality or objectivity in decision-making.
4. Participation in **Data and Safety Monitoring Boards (DSMB) for competing trials** or similar role.	**Yes** Privy to confidential data of specified and other trial(s). Likely to cause conflict with that member's participation on the DSMB as well as on platform EBCO.

The avoidance of any perception that members of a EBCO may be biased is important for the credibility of the decisions made by the EBCO and for the integrity of the platform. All possible competing interests should be disclosed. In many cases simple disclosure up front should be sufficient. Otherwise, the (potential) EBCO member should remove the conflict or stop participating in the EBCO.

Declaration of Potential Competing Interests

Lead/Chief Investigator on competing trial (national or international) with specific contract with industry partner	◯ Yes ☐ No
You or your partner OR immediate family member have stock ownership in any commercial companies involved in the trial or from which an asset is being considered for inclusion. Assets that have been excluded by the EBCO should be disclosed but would not be considered a Conflict of Interest.	◯ Yes ☐ No
Stock transaction in any commercial company involved (if previously holding stock)	◯ Yes ☐ No
Consulting arrangements with the Sponsor or their representative	◯ Yes ☐ No
Consultancy agreements with a pharmaceutical company or for-profit industry partner whose work is related to the study under discussion	◯ Yes ☐ No
Career or personal research funding that is dependent on the development product or technique assessed by trial	◯ Yes ☐ No
Intellectual conflict e.g. strong prior bias to the trial's experimental arm	◯ Yes ☐ No
Involvement in regulatory discussions or consulting relevant to the trial (e.g. member of PDCO or FDA)	◯ Yes ☐ No
Investment (financial or intellectual) or career focus or dependency in competing products	◯ Yes ☐ No
Other competing interest not listed (intellectual / financial / personal / professional)	◯ Yes ☐ No

If you have answered yes to any of the above options, please provide further detail:

	Initial to agree:
I have read, understood and agree with the EBCO Charter version xxxxxx	
I agree to join the EBCO for this trial	
I agree to treat all trial documentation, data and discussions confidentially	

Print Name:

Sign Name:

Date: DD / MM / YYYY

Please return this form with a current signed and dated copy of your CV to xxxxxxxxxxxxxx