



Industry Engagement Guidelines

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Background

The International Coalition to Eliminate Hepatitis B is a global initiative aiming to support the discovery of a safe, affordable, scalable and effective cure, available to all persons living with CHB. To achieve this, our vision is to create an international, independent, research-based and patient-centered forum in order to coordinate, promote and foster collaborative arrangements working towards a cure for HBV. The Coalition is not an incorporated entity. The Doherty Institute act as ICE-HBV secretariat under the legal responsibility of the University of Melbourne. ICE-HBV does not perform research per se, but engages in research coordination and promotion.

ICE-HBV has a real interest for collaboration with private sector entities, specifically from the pharmaceutical and diagnostics industries but also with companies from other sectors. Some pharmaceutical, diagnostics and IT companies have a direct commercial stake in HBV cure as suppliers of medical products and have expressed interest to work with ICE-HBV. Other sectors may be motivated to engage with ICE-HBV because their workforce, their clients or the communities in which they operate are impacted by the epidemic: They seek a platform to demonstrate good corporate citizenship.

ICE-HBV considers the private sector a core participant in search for an HBV cure, in addition to academia, community, governments, and civil society. After the publication date of ICE-HBV first scientific strategy, ICE-HBV will seek to work with private sector entities in three ways: as sponsors, as donors, and as participants in activities (see section 3 below). To ensure mutually beneficial relationships free of conflicts of interest, it is important to provide clarity for all involved on

opportunities, limitations and accountabilities. The present guidelines have been developed for this purpose.

1. Guiding principles

1.1 Shared goals

ICE-HBV collaborates with private sector entities whose strategic goals are in good faith aligned with the ICE-HBV vision of discovering a safe, affordable, scalable and effective HBV cure.

1.2 Added benefit

Collaborations with private sector entities are expected to result in additional resources for ICE-HBV activities including financial or in-kind contributions or the provision of technical expertise.

1.3 Avoid conflict of interest

In all collaborations with private sector entities, ICE-HBV will carefully assess the potential for conflicts of interest at both the institutional and individual member level. Any potential conflict of interest will be properly identified, resolved and disclosed.

1.4 No exclusivity

ICE-HBV does not grant exclusive rights to one private sector corporation or industry sector in any project or programme: Every activity for which private sector cooperation is invited is open to multiple organisations, including to direct competitors in specific market segments. ICE-HBV actively seeks the involvement of multiple organisations.

1.5 Endorsements

In principle, ICE-HBV does not endorse any particular private sector entity, its activities, products or services.

1.6 No corporate influence on strategic direction or scientific recommendations

Private sector collaborators will not have the opportunity to participate in decisions over ICE-HBV strategic direction or scientific recommendations. Private sector collaborators can be invited to provide advice on technical and programmatic matters as per clause 3.2.

1.7 Transparency

ICE-HBV is committed to the principle of transparency of process and decision-making. With respect to private sector collaborations ICE-HBV will at a minimum disclose:

- The existence of the collaboration
- The identity of the collaborators
- The nature and scope of the collaboration

All active collaborations between ICE-HBV and private sector entities will be listed on ICE-HBV website (www.ice-hbv.org).

2. Eligibility

2.1 Responsible business practices

ICE-HBV aligns to responsible business practices based on universal principles of human rights, labour, environment and anti-corruption. ICE-HBV will only collaborate with organizations that commit to adhering to these principles in their day-to-day business wherever they have a presence, and strive to reflect these principles in their policies and procedures.

ICE-HBV works only with private sector entities who do not actively or implicitly support:

- discriminatory workplace practices that include, but are not limited to, real or perceived HBV status, sexual orientation, gender identity, mental or physical disability, age, race/ethnicity, marital status, family or care giver's responsibilities, pregnancy, religion;
- views that would negatively impact people living with HBV

3. Types of engagement

3.1 Grants & Sponsorship

ICE-HBV will seek Corporate supporters award grants in cash and sponsorship in cash and in-kind based on a request developed by ICE-HBV secretariat. Unrestricted grants are preferred and usually support ICE-HBV core activities. Some grants can be restricted to a specific activity (research project, conference participation, organisation).

The objectives and implementation approach of each grant will be defined by ICE-HBV. Private sector entity representatives will not have decision-making authority with regard to project/programme implementation. Collaborators will be duly acknowledged as a donor/grantee but it will not receive direct benefits.

3.2 Participation in activities

Representatives of private sector entities may participate in ICE-HBV activities to provide technical or programmatic expertise during consultation meeting and specific project meetings (when public-private collaborations are established for specific research projects, such as the cccDNA assay standardization group). They will not be part of decision making process involving general strategy and scientific positions of ICE-HBV. They will not have access to scientific working group meeting proceedings nor will they attend general working group meetings unless they are specifically invited by the working group.

Any intellectual property (IP) arising from the work of ICE-HBV groups will remain the exclusive domain of ICE-HBV investigators and their institution of origin, according to their relative participation to the production of IP.

4. Processes

4.1 Due diligence

ICE-HBV will carry out a due diligence review before a collaboration agreement is signed to ascertain that the partner's values and business practices align with the principles described in this document. The process will consist of a review of publicly available information to assess eligibility and alignment of goals as per sections 1 and 2 above.

Subject to the approval by the ICE-HBV Governing Board, the ICE-HBV secretariat is responsible for implementing the process and providing a recommendation to the authorized signatories to a collaboration agreement on whether or not to enter into the collaboration.

4.2 Agreements

Each donor or sponsor relationship with a private sector corporation will be formalized in an appropriate agreement that describes the roles and responsibilities of both parties, any financial benefits for ICE-HBV, agreed acknowledgment of the collaboration along with specific benefits (in the case of sponsorships), if any, use of each party's name and logo by the other party, intellectual property stipulations, etc.

Collaboration Agreements with private sector entities will require the private sector entity to confirm alignment with the principles of responsible business practice as described in 2.1 above.

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