

DRAFT IHCC Guidance for Collaboration with Industry

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Overview –

The purpose of the Draft IHCC Guidance for Collaboration with Industry is to support the establishment of IHCC collaborations with industry partners by providing guidance that promotes the IHCC vision and values within any collaborative agreement. The document explicitly develops the IHCC values of open and timely access to research outputs and activities through transparent processes and practices. In order to provide flexibility for different forms and models for partnerships with industry, this document is intended to provide a resource for IHCC Members in their development of formal collaboration agreements with industry partners.

Draft Guidance Highlights –

- Three collaboration “types” for collaborations with industry are defined within the document, as well as activities that are not subject to the guidance’s expectations.
- Pursuit of collaborative activities should be undergirded by a set of “first principles”.
- Three ‘Points to Consider’ are outlined that any IHCC partnership agreement should address: Fairness & Equity, Transparency, Timely & Open Data Dissemination.
- A draft IHCC Collaboration Checklist is proposed as a resource to IHCC Members to consult as they develop IHCC partnership agreements and before any collaborative work begins.
- Additional discussion of issues to maintain and monitor IHCC collaborations is also provided.

Substantive Updates –

- More explicit reference is made to reciprocal interests of academic/non-profit and industry partners in forming collaborations and respective issues to be addressed through their supporting agreements (e.g., at Line 9-10).
- Clarified that the Guidance applies to approved IHCC Projects involving industry partners (as distinct from collaborations that cohort members may establish with industry partner outside of their IHCC activities).
- Noted that more than one type of collaborative relationship may apply to partnerships formed to support IHCC Projects.
- Modified language within the “first principles” (Lines 40-52) to be inclusive of a broader range of examples to realize “value” or “capacity” for partners and other study stakeholders (e.g., research participants or study populations).
- Clarified that the expectation for public postings regarding collaboration agreements was limited to a general summary and not intended to include detailed terms or other information that may be relevant to proprietary concerns.

DRAFT IHCC Guidance for Collaboration with Industry

1. Scope and Purpose of this Guidance

The purpose of this guidance is to support collaboration(s) between International HundredK+ Cohorts Consortium (IHCC) Cohort Members and industry partners as part of an IHCC Project (i.e., a project approved by the IHCC Scientific Projects Sub-Committee). This guidance also serves to ensure that any IHCC collaboration is conducted with integrity, any interests are open and transparent, any conflicts are managed appropriately, and that the respective commitments and considerations of all participating parties are appropriately balanced. This guidance covers any research or research-related activity pertaining to an approved IHCC Project that involves collaboration with one or more industry partners.

The term industry is used herein to refer to a broad range of sectors, usually private, which are involved in some form of commerce either to make a profit or to support a business. Per the IHCC Membership Agreement, IHCC Cohort Members may be from industry or from non-industry sectors. Likewise, for the purposes of this guidance, industry partners can be IHCC Industry Members or non-IHCC members. Non-profit partners may collaborate with the IHCC by becoming Affiliate Members, as outlined in the IHCC Membership Agreement.

Outside the scope of this guidance, assuming no potential conflicts of interest are present, are:

- new or existing direct collaborations between an IHCC Cohort Member and industry partners as part of non-IHCC activities; and
- new or existing collaborations between IHCC Cohort Member investigators and industry partners as part of non-IHCC activities.

There are three broad types of collaborations between IHCC Members and industry partners to be guided by this document (more than one may apply):

1. Collaboration between established industry- and non-industry-led cohorts (e.g., between IHCC Cohort Members);
2. Collaboration among IHCC Cohort Members and an industry partner(s) to generate data or participate in analytic activities (e.g., between IHCC Members and external industry partners); or
3. Provision of financial and/or other resources by an industry partner(s) to support an IHCC Project in exchange for access to data or analyses generated through the resultant study.

The guidance in this document is based on a set of 'first principles' that should underlie any IHCC collaboration, including those with industry partners.

1. Collaborative activities should offer potential value to participating partners (e.g., present a unique scientific opportunity or potential for benefit to be realized for cohorts, their study populations, or underserved communities around the globe, provide for cohort access to financial or other resources, or to other benefit sharing prospects that will advance participating partners' goals and IHCC strategic objectives, etc.);
2. Collaborations should seek to include activities/resources that build capacity or provide resources for participating partners where appropriate (e.g., infrastructure development,

47 equipment or technology access, research service provision, expertise sharing or
48 researcher training, general workforce development, etc.); and

49 3. Collaborative projects should promote inclusion among IHCC members and industry
50 partners in leadership for scientific design, study conduct, and publication (e.g.,
51 methodologies selected, assignment of project roles and responsibilities, authorship
52 determinations).
53

54 Please note that this guidance is general and specific questions may need to be raised with the
55 IHCC Scientific Steering Committee based on a particular IHCC Project Proposal involving an
56 industry partner(s). This guidance is subject to updates as the IHCC or any of its governing
57 policies evolve.
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60 **2. Points to Consider for IHCC-Industry Collaborations**

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62 IHCC aims to support links between IHCC Cohort Members and industry partners where
63 collaboration is consistent with the IHCC vision to enhance our understanding of the biological,
64 genetic, social and environmental basis of disease and to improve population health. Working
65 with industry partners is not a requirement of IHCC collaborations and/or projects.
66

67 The following points to consider should be used to frame the development and guide the
68 progression of every IHCC partnership with industry.
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70 *Note:*

71 The IHCC recommends against forming collaborations involving industry partners in an IHCC
72 Project when those partners engage in or contribute to programs or products involving the
73 production, sales, and/or marketing of tobacco or nicotine products.
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75 **2.1 Fairness and Equity for All Substantially Contributing Parties.**

76 Determinations regarding ‘fair and equitable’ may vary by collaboration based upon relevant
77 stakeholders. Establishing mutually agreed upon, publicly documented terms for collaboration
78 prior to engagement in the collaboration will be key to producing high-quality studies likely to
79 lead to opportunities for improving health for all (see also Section 3).
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82 A Memorandum of Understanding, or other binding agreement, among participating IHCC
83 Cohort Members and an industry partner(s) should be agreed to prior to initiating any
84 collaborative work pertaining to an IHCC Project. This collaboration agreement should set out
85 the specific terms of the partnership, including any intellectual property management and
86 revenue distribution arrangements, if relevant. A signed copy of the collaboration agreement
87 once agreed upon by all relevant parties (i.e., any party contributing substantively to the aims
88 of the collaboration), should be provided to all parties. In addition, for transparency of the
89 IHCC activity, a lay summary of the Project’s scientific aims along with a general summary of
90 the agreement (respecting any proprietary concerns) should be posted on the IHCC webpage.
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93 **2.2 Transparency in Aims and Interests.**

94 Disclosing the aims and interests of all parties substantively contributing to a research
95 collaboration as called for in Section 2.1 will help to alleviate any real or perceived conflicts of
96 interest. Further, conflicts of interest, whether real or perceived, can be a threat to the integrity
of and trust in research results.

97
98 To promote openness and transparency, all collaborating parties named in a collaboration
99 agreement involving an IHCC Project should declare any financial or non-financial activities or
100 relationships that could be deemed or be perceived to affect decisions about the IHCC
101 Project. For the purposes of this guidance, a collaborating party includes those individuals
102 contributing substantively to the IHCC Project on behalf of an IHCC Member (irrespective of
103 academic, non-profit, or for-profit status). Summaries of such declarations should be publicly
104 posted along with the summary of the collaboration agreement per 2.1 above.

105
106 These declarations are anticipated to focus on pecuniary interests (e.g., employment,
107 contracts, other company associations, as well as broader interests, such as trust funds,
108 investments, and assets), or other matters consistent with local standard practices or policies
109 regarding conflicts of interest (e.g., funding from industry/private partners or any personal
110 payments to IHCC study/project leaders, such as consultancy fees, etc.). Existing standards,
111 such as the disclosure expectations for authors from the [International Committee of Medical
112 Journal Editors](#)¹ or the code on relationships from the [European Federation of Pharmaceutical
113 Industries and Associations](#),² may be useful for IHCC Cohort Members to consider as well as
114 collaborators' local practices or policies in documenting any potential conflicts of interest with
115 regard to an IHCC Project.

116
117 It is possible that IHCC Cohort Members and an industry partner(s) could be involved in
118 separate and non-IHCC-related discussions about potential collaborations or projects outside
119 the scope of this guidance or the IHCC. To promote transparency, it is advised that
120 participating cohorts or industry partners in an IHCC Project disclose that such parallel
121 negotiations exist, but it is not expected that the substance or terms of those discussions be
122 disclosed unless they relate to a specific IHCC collaborative activity.

123 124 **2.3 Timely and Open Dissemination of Research Data and Findings.**

125 A critical aspect of realizing the IHCC vision to facilitate translational research that will be
126 maximally utilized to enhance scientific understanding of the biological, environmental and
127 genetic basis of disease and to improve population health is timely and open dissemination of
128 research results. Integral to this vision is making study data available in an appropriate
129 manner (e.g., via open or controlled-access data repositories; see IHCC Data Sharing
130 Principles for further information). IHCC understands that industry partners may require a
131 timeframe of exclusive access to study results. However, this timeframe should be agreed
132 upon by all parties in advance of the study and should be appropriate for the type of study,
133 data generated, and aims of the collaboration. IHCC recommends making research data and
134 analyses accessible through appropriate mechanisms generally no later than 12 months after
135 their generation and completion of initial quality control or at the time of first publication,
136 whichever occurs first.

137
138 Consistent with the IHCC Membership Agreement all IHCC collaborations should make
139 products, services, or other intellectual property developed through any IHCC collaborative
140 activity (as defined in a collaboration agreement per Section 3 below) available in a manner
141 that promotes freedom to operate and the potential for maximum public benefit to be realized.

¹ For additional details on expectations see the ICMJE Disclosure form available through
<http://www.icmje.org/conflicts-of-interest/>.

² For information on the body of ethical rules agreed to by members of the European Federation of
Pharmaceutical Industries and Associations for their interactions with healthcare providers, healthcare
organizations, and patient organizations see <https://www.efpia.eu/relationships-code/the-efpia-code/>.

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3. IHCC Industry Collaboration Checklist

To support the principles and values of the IHCC, IHCC Cohort Members should utilize the following documents in addition to this Guidance to facilitate the development of and agreements to collaborations with an industry partner(s):

- i) IHCC Membership Agreement
- ii) IHCC Publication Policy
- iii) IHCC Data Sharing Principles

The IHCC Industry Collaboration Checklist (ICC, see Appendix 1) is intended to guide the establishment of a partnership and support the drafting of collaboration agreements involving IHCC Members and industry partners (see Section 2.1). The ICC is intended as a resource for IHCC Cohort Members to review *before* an IHCC Project begins to ensure that IHCC principles and guidance will be upheld throughout the collaborative activity and documented in any industry partnership agreements. The ICC is based upon the Points to Consider identified in Section 2 above and is designed as a checklist to allow for the flexibility necessary to address the range of possible industry contributions to an IHCC Project (e.g., funding, in-kind contributions of staff time, specialized assets, or other resources).

Agreements between IHCC Members and industry partners should clearly specify terms and arrangements among partners for:

1. Respective responsibilities among parties;
2. Governance for the collaboration;
3. Regulatory approvals, as relevant;
4. Indemnity;
5. Definition of possible intellectual property that may be generated, as well as any expected rights to such among collaborating partners, if any;
6. Reporting to key stakeholders (e.g., funders, or the IHCC Scientific Steering Committee);
7. Access to data or samples that will be provided among partners; and,
8. Plans to meet IHCC expectations for broad and timely access to data and findings generated through the partnership.

Industry partners of any size may participate, and multiple industry partners may contribute to a single IHCC Project collaboration or collaborative activity.

4. Maintaining and Monitoring the Principles

4.1. Publishing Details of Study Design

IHCC Scientific Projects involving industry partners should be designed in a way that minimizes possible sources of bias or perceived bias from any IHCC Member or partner as far as practically possible (including providing transparency regarding any potential issues per Section 2.2). To increase public confidence in this process, research protocols should be

186 made publicly available as soon as possible, or no later than the time of any publication on the
187 collaborative work.

188

189 **4.2. Accepting Gifts and Payments from Industry**

190 Accepting gifts and other types of financial support beyond that specified in the collaboration
191 agreement for the relevant IHCC Project will be deemed a conflict of interest. It is often
192 standard practice for industry to provide hospitality, but researchers should not accept any
193 funds that are not covered by the collaboration agreement and/or openly declared. This
194 extends to declining offers of travel reimbursement or sponsorship from industry to present
195 research findings at an event.

196

197 **4.3. Research Governance**

198 This guidance does not cover all aspects of IHCC research governance as set forth in other
199 IHCC documents and policies and assumes all participating parties will adhere to their
200 institutional research policies and governance requirements, as well as all relevant local and
201 national laws.

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203 **Appendix 1**

204 **IHCC Industry Collaboration Checklist**

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206 The IHCC Industry Collaboration Checklist (ICC) is intended to guide the establishment of a
207 collaboration involving IHCC Cohort Members *before* an IHCC Project begins to ensure that
208 IHCC principles, policies, and guidance will be upheld throughout the collaboration.

209
210 Within a binding collaboration agreement document, IHCC Cohort Members and industry
211 partners should clearly specify terms and arrangements among partners pertaining to:

- 212
213 **Collaboration Type (more than one may apply):**
- 214 Collaboration between established industry- and non-industry-led cohorts (e.g., between
 - 215 IHCC Cohort Members)
 - 216 Collaboration among IHCC Cohort Members (industry or non-industry based) and an
 - 217 industry partner(s) to generate data or participate in analytic activities
 - 218 Provision of financial or other resources by an industry partner(s) to support an IHCC
 - 219 Project in exchange for access to data or analyses generated through the resultant study
 - 220

221 **Basic Partnership Information:**

- 222 Identification of substantially contributing parties (e.g., *IHCC Members, industry partners,*
- 223 *IHCC Cohort collaborators or funders*)
- 224 Names of IHCC Member Primary Investigators (PIs) and any PI-designated leads for the
- 225 specific IHCC Project
- 226 Names of the primary points of contact from industry partners for the IHCC Project
- 227 Regulatory approvals, when relevant (e.g., *ethics approvals*)
- 228 Indemnity provisions, if any
- 229

230 **Fairness and Equity for All Substantially Contributing Parties:**

- 231 Respective responsibilities of collaborating parties (e.g., *data submission or generation,*
- 232 *data processing or analysis, financial or other resource provisions*)
- 233 Governance for the collaboration (e.g., *participation in or leadership for project oversight*
- 234 *and decision making*)
- 235

236 **Transparency in Aims and Interests:**

- 237 Reporting plans to key stakeholders (e.g., *IHCC project funders, IHCC Scientific*
- 238 *Steering Committee, IHCC Members*)
- 239 Access to be provided to partners (e.g., *summary or individual-level data, biospecimens*)
- 240 and through what mechanisms (e.g., *individual or project-wide access through cohort-*
- 241 *specific processes*)

242 Timeline for access to resources or data among partners

243

244 **Timely and Open Dissemination of Research Data and Findings:**

245 Intellectual property issues, if any (*e.g., exclusive data access periods, designation of*
246 *data or findings generated as precompetitive*)

247 Milestones to meet IHCC expectations for broad and timely access to data and findings
248 generated through the partnership (*e.g., first publication anticipated within 18 months of*
249 *data generation*)

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