



# THE COHRED FAIRNESS INDEX™

## GLOBAL CONSULTATION DOCUMENT

(Version 2)

Printing Date: 16 April 2015

Version 1 of this document was produced for the first global consultation, which was held from 21 January – 27 March 2015. This second version of the CFI document has taken into account all comments made during the first, ‘virtual’ global consultation, and is produced to inform the first, global multi-stakeholder meeting that will take place in London on 17-16 April 2015.

The content of this work is prepared to obtain comments from all stakeholders in international research for health on the establishment of the COHRED Fairness Index (CFI) – intended to create a certification system that promotes fair practices, transparency and accountability in research partnerships for global health.

**Feel free to share the content of this work on your website, send it to contacts, or make it wider available in any other manner.**

For any questions, comments or suggestions please feel free to contact:

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## COUNCIL ON HEALTH RESEARCH FOR DEVELOPMENT (COHRED)

COHRED, the Council on Health Research for Development, is a global, non-profit organisation whose goal is to maximize the potential of research and innovation to deliver sustainable solutions that promote health, equity and development, especially for people living in low and middle-income countries. For more information, please visit our website <http://www.cohred.org>

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## Executive Summary

This document is meant to build stakeholder understanding of and engagement with the **COHRED Fairness Index (CFI)**. It constitutes a second public version to elicit substantive comments that will increase the credibility and effectiveness of this Index focusing on international health research and innovation partnerships. Circulation is global, and directed at all parties that have an interest in high quality, responsive and responsible health research collaborations.

**The CFI is envisaged as an actively managed certification system** based on best practices in international collaborative research and innovation for health.

**The CFI intends to certify the ability to engage in and sustain fair research and innovation partnerships.**

The CFI can be operated at *project, institutional, national (or international)* levels, as well as at *partnership* level. To get started, it is proposed **to begin with certification of conditions essential to fair research and innovation partnerships at institutional and national (international) level**. At a future stage, application to project and partnership level will be developed.

**Its ultimate goal is to improve the alignment of interests of all partners in global health research and innovation**, and to increase the capacity of low and middle-income countries in particular **to optimize the use of research and innovation to improve health, reduce inequity and stimulate socio-economic development**.

The design of the CFI was steered by a multi-stakeholder Technical Working Group (TWG), which engaged in an interactive, bi-weekly consultation process between September and November 2014.<sup>1</sup> This second version was prepared for the first multi-stakeholder, global consultation meeting on 16-17 April 2015, at the Wellcome Trust in London, in which 80 key people will further reflect on the CFI in a face-to-face manner. Following the meeting, a third version of the document will be prepared by COHRED's core writing group and a (New) Technical Working Group for another round of global consultations. Finally, **it is expected that the CFI will be launched in October 2015**.

**We believe that the CFI is only as good as the value it adds to the work of all stakeholders in research and innovation for health around the world.** For that reason, we are actively encouraging contributions to improve alignment of the principles and scope of the CFI with the direct needs of all stakeholders. **We also ask you to consider endorsing the need for and process of establishing the CFI.** More endorsements will facilitate easier implementation!

Any comments, feedback or questions and endorsement statements are welcome at any time and can be sent to [musolino@cohred.org](mailto:musolino@cohred.org) or via the CFI website <http://cfi.cohred.org>

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<sup>1</sup> For names and affiliations of the members of the Technical Working Group please consult <http://cfi.cohred.org/technical-working-group/>

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## Definitions and Abbreviations

### **Beneficiaries**

The last entity in the value chain that benefits from the impact of the COHRED Fairness Index.

### **Benefits of Research and Innovation**

Refers not only to academic publications, guidelines, strategies and products, but also the individual or institutional increase in research capacity and research competitiveness, intellectual property, increased potential for spin-off business and socio-economic activity.

### **Collaborative Research Partnerships**

Cooperation between researchers and research institutions to address complex problems in research and innovation for health. In global health context, such partnerships often imply greatly unequal finance, human resource and contracting capacity which the CFI intends to re-balance. Such 'unequal partnerships' are not limited to research in global health – they can occur anywhere. The CFI will have global appeal to all such situations.

### **Domain**

The area in which the CFI intends to achieve an objective. This is distinct from an indicator, which measures whether or not an objective has been achieved.

### **Equity**

In the context of this paper, equity refers to the fair distribution of all the benefits of research for health to all partners engaged in a given partnership.

### **Fair**

We define fairness in terms of indicators that form the basis for certification. The collective set of indicators are the pragmatic definition of fairness in international partnerships in research and innovation. These can be modified overtime by the Technical Working Group.

### **Fair Research Contracting**

A guidance tool for contractual negotiations developed by COHRED for low middle-income Country institutions in research and innovation for health. See [www.cohred.org/frc](http://www.cohred.org/frc)

### **Innovation**

Transforming knowledge resulting from research into practical and scalable solutions. Distinction is often made between 'social' and 'technical' innovation.

**Research** is generation of new knowledge through systematic investigation.

### **Stakeholder in Research**

All who are engaged in the research and innovation that impact substantively on health and health equity. A non-exhaustive list includes: academia, researchers, international organisations, pharmaceutical companies, other companies involved in research for health – diagnostics, genetics, technology, services, insurance, 'big data' collectors, government institutions, NGOs, donors, philanthropies, research sponsors, concerned citizens.

### **Technical Working Group**

A multi-stakeholder consortium contributing towards the development of the COHRED Fairness Index that was engaged with COHRED in bi-weekly consultations from September to November 2014

### **Users**

The beneficiary that puts into practice the guidelines of the COHRED Fairness Index for the purpose of assessment and certification in the field of research for health.

## **Abbreviations**

CFI	COHRED Fairness Index
COHRED	Council on Health Research for Development
Fiocruz	Oswaldo Cruz Foundation, Brazil
FRC	Fair Research Contracting
IAVI	International Aids Vaccine Initiative
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
ISEAL	International Social and Environmental Accreditation and Labelling
KEMRI	Kenya Medical Research Institute
LMIC	Low and Middle-Income Country
M&E	Monitoring and Evaluation
TWG	Technical Working Group
WHO/TDR	World Health Organization / Tropical Disease Research

# Introduction and rationale

## **The context:**

- Billions of dollars of health research funding
- Hundreds of thousands research projects
- Tens of thousands researchers
- Thousands of research partnerships
- A thousand and more research Institutions, businesses, universities, non-profits and public private partnerships
- Close to two hundred governments
- And – perhaps – over 100 major philanthropic funders

Operate the field of research for health and research for global health.

## **The issue:**

- Few if any globally accepted standards for collaboration, partnerships, addressing equity in benefit sharing, capacity transfer, fairness, transparency and accountability exist.

## **The solution:**

- The COHRED Fairness Index is aimed at providing an actively managed certification system to optimize the ability to engage in and sustain fair research and innovation partnerships around the globe.

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Improving health, increasing longevity and deepening well-being requires sustained and growing investments in research and innovation for health. This applies as much to high as to low and middle-income countries and populations. While much health gains can be achieved through improving health systems and service delivery, the major gains in longevity, health and well-being – and sustaining these – will require increasing research and innovation. In turn, such research and innovation will have to rely increasingly on effective multi-stakeholder and transnational partnerships to deal adequately with complexity, scale and equitable access.

The figure below comes from the website of Bill & Melinda Gates Foundation's Grand Challenges shows that of the 1698 grants in 80 different countries the majority is distributed outside Africa even though most of these Challenges focused on solutions for Africa. The CFI wants to make a major contribution to improving the research and innovation capacity of Africa, and LMICs in general, to reduce and eliminate this imbalance.



Figure 1. (<http://grandchallenges.org> accessed on 4 April 2015).

The picture above is reinforced by other evidence, including a recent article in *Nature*<sup>2</sup> reported high-level results from the Nature Index to show the footprint in the life sciences, physical sciences, chemistry, earth and environmental sciences in the main geographical zones around the world, showing the under-representation of low and middle income countries generally, and for Africa in particular.

From the article:

[Global overview](#)

*Nature* 515, S56–S57 (13 November 2014) | doi:10.1038/515S56a

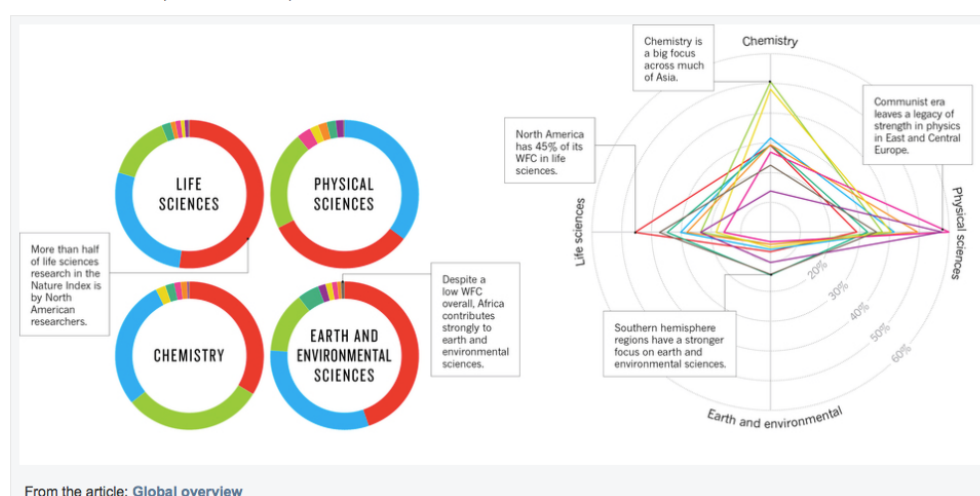


Figure 2. Global Overview, *Nature*, 13 November 2014

Low and middle-income countries face serious hurdle to bring their research and innovation systems up to global competitiveness and excellence – their system for research and innovation are sometimes not even sufficiently robust to address their own priority health challenges. Years of global support for health research in low and middle income countries have resulted in many products, many improved services, many lives saved but have not systematically, and at times not

<sup>2</sup> *Nature* 515, S56–S57 (13 November 2014) doi:10.1038/515S56a. Published online 12 November 2014



even substantially, improved the systems that countries need to prioritize, conduct, commission, partner or finance research and innovation and to translate results into effective policy, practice and products.

But the CFI does not just apply to low and middle income countries. As the borders between ‘developing’ and ‘developed’ countries are blurring, imbalances in research and innovation relationships are evident also within high-income countries and regions. A certification system that would help make distribution of all benefits of research and the research and innovation enterprise better will be instrumental in growing the global capacity to deal with increasingly complex health challenges – when and where they occur.

Imbalanced partnerships put partners at risk of unintended harm to people – through omission or commission, as there may be insufficient checks or regulatory capacity in the system. In addition to individual harm that may result, researchers – research funders – research institutions and business taking part in such partnership may run the risk of serious damage to their reputations in the countries concerned and even globally.

#### An Effective CFI Should Result In:

1. **Greater health research & innovation capacity** in low and middle income countries, and even worldwide, to deal with more complex problems and provide more comprehensive solutions;
2. **Minimisation of risk** of research to people;
3. **Reduction of reputational risk** to all partners in the research process and to health research itself.

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The purpose of developing the COHRED Fairness Index (CFI) is to establish a cost-effective global certification system that will encourage the attainment of the highest standards in global best practices in international partnerships for research and innovation for health.

The primary rationale for embarking on the creation of the CFI was to (measure and) **incentivize international research and innovation partnerships involving researchers, donors, industry, institutions and research sponsors from high-income countries, on the one hand, and those of low and middle-income countries on the other hand**. However, throughout our consultation it became clear that the CFI should play a similar role in such partnerships everywhere.

Many bi-lateral research and innovation partnerships go to great lengths to negotiate ‘basic-cooperation-agreements’, often delaying work with months, if not years. (see, for example, “Further Readings” 18, 19) **An effective CFI should be able to greatly reduce the negotiation time for partnership agreements while improving their quality and sustainability.**

Typically, the private sector has designed a seamless transition from research to innovation – as in “R&D” – the link is essential to successful business operations. However, this often not the case in the public and philanthropy sector, which are highly compartmentalised between structures and finance for research on the one hand, and structures and finance for innovation, on the other. **The CFI seeks to reduce this divide to ensure that research and health impact become more closely linked.**

In response to these and many other arguments for a CFI (see the CFI website for cases, testimonials, and endorsements, for example), COHRED embarked on the development of an actively managed certification system that will incentivise the development and use of best practices in international partnerships in research and innovation for health.

**The purpose of this document is primarily to provide all future users with the opportunity to contribute in the development of an actively managed certification system that will add value to their on-going research and innovation efforts and that of others.**

In short, the COHRED Fairness Index (CFI) as proposed is:

**An actively managed certification system to increase the ability of all stakeholders to engage in and sustain fair research and innovation partnerships.**

- Increase fair distribution of effort and benefits, transparency, accountability and relevance to global health
- Encourage all users to gradually improve collaborative partnerships

The CFI will consider existing guides, tools and international conventions related to research and innovation and take from them what is relevant for the CFI<sup>3</sup>. In addition, where there are no guides or clear gaps in existing guides, the CFI will design new standards and indicators of best practices for use in the certification system.

**Therefore the CFI will consist of – *at a minimum*:**

- Domains or areas in which the CFI should impact
- Indicators to be able to measure progress in these ‘domains’
- A measurement process
- An independent assessment process
- A reporting system
- And a seal of approval (certification)

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<sup>3</sup> For example: KFPE ; ICH-GCP ; UNAIDS ; CIOMS ; Nagoya Protocol ; The Global Innovation Index – WIPO ; ESSENCE good practice document; Helsinki Declaration, and more)

### Limitation of Scope of CFI – at inception:

The CFI can measure fairness at project/program level, institutional level and at country level, and it can assess the quality of research and innovation partnerships. To be clear: at the level of Project/Programme – Institution – Country, the CFI will certify conditions that are essential or conducive to engage in and sustain fair research and innovation partnerships. At these levels, assessment of only one partner can never assess the partnership itself.

For example: the presence and use of enabling policies at national level or having a competent research management office or IP-trained lawyer at a university will greatly increase the possibility that the contracts that involve this university will be 'fair' – but, clearly, it is not a fail-safe guarantee.

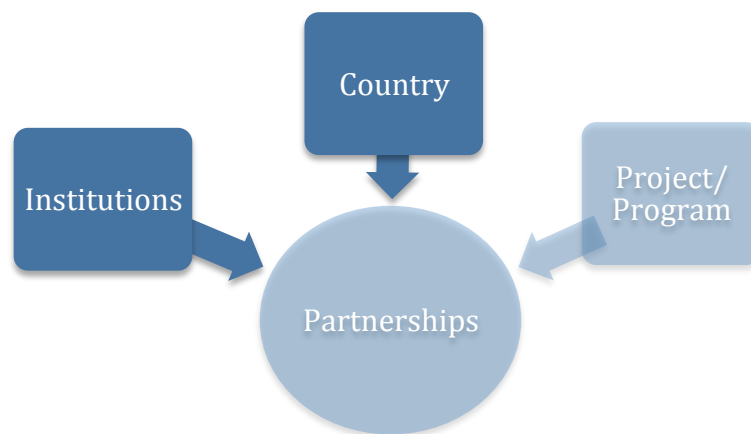


Figure 3. Limitation of Scope of CFI – at inception. Colour key: *The institutional and national levels are in bold: these are the ones that the CFI will look at first. The projects and partnerships (in transparent) will be looked at in the future.*

At project, institution and country level, the CFI can only measure conditions that are essential to fairness in research and innovation. It cannot measure the quality of the partnerships itself by engaging only one partner or one stakeholder. Measuring the quality of partnerships is the long term ideal, but the complexity of doing so is beyond our current capacity. Similarly, to measure hundreds and thousands of projects is beyond our current capacity.

**Therefore, at this stage of its development, we propose to limit the application of the CFI to certification at national and institutional level.**

## Building the COHRED Fairness Index

An actively managed certification system to increase the ability of all stakeholders to engage in and sustain fair research and innovation partnerships. The CFI process will be independent, transparent and should address the key domains to be defined in the consultation process

To ensure it has wide credibility, we adhere to the following principles (adapted from ISEAL Credibility Principles<sup>4</sup>).

1. Improvement
2. Relevance
3. Rigour
4. Engagement
5. Impartiality
6. Transparency
7. Accessibility
8. Truthfulness
9. Efficiency
10. Operational Sustainability

**Comments are specifically invited to modify the CFI in ways that make it an even better reflection of these principles. Perhaps there are other, more relevant principles as well.**

There are 5 generic ways in which to pursue ‘fairness in partnerships’ – presented below in a ‘hierarchy of increasing pressure to implement’ :

### **1. Raising Awareness:**

For example, through publications and conference proceedings. (*see “Further Readings” 18-20*)

### **2. Guidelines / Consensus of Best Practices**

The closest standard available in global health research are the “11 Principles and 7 Questions” printed in the “Guide for Transboundary Research Partnerships” published by The Swiss Commission for Research Partnerships with Developing Countries (KFPE), as a set of principles for voluntary use in science in general.<sup>5</sup> These eleven principles of research partnerships proposed as guidelines for grant applicants and funding agencies are an exemplary effort in fostering balanced partnerships between developing countries and low middle-income countries.

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<sup>4</sup> ISEAL Alliance - <http://www.isealalliance.org> - is a global leader in design of user-oriented certification processes and systems. Neither COHRED nor the CFI is a member of the ISEAL Alliance at this time, but we strongly support their principles, approach and transparency in preparing the CFI

<sup>5</sup> [http://www.naturalsciences.ch/organisations/kfpe/11\\_principles\\_7\\_questions](http://www.naturalsciences.ch/organisations/kfpe/11_principles_7_questions)

### 3. Practical Tools and Templates

Beyond awareness and guidelines, the availability of practical tools that users have easy access to will greatly facilitate implementation of practices that make research and innovation partnerships ‘more fair’. For example, COHRED developed the “Fair Research Contracting (FRC)” initiative<sup>6</sup> to provide guidance documents and technical support for institutions without trained contracting staff to negotiate better collaboration agreements and contracts and provide connection to intellectual property advisors, To re-emphasize the applicability of the CFI not just to low and middle income countries, we also refer to the United Kingdom’s effort to improve research contracting between UK universities and private sector – the Lambert toolkit.<sup>7</sup>

### 4. (Actively managed) Certification

Certification, labeling and reporting are active ways in which adherence to principles of best practices can be encouraged without resorting to law or international convention. We were not able to find any such system in the field of research and innovation for health. This is part of the rationale to create CFI as an ‘actively managed, global certification system’.

### 5. Legal Obligation

For example, in November 2014, the 50<sup>th</sup> UN member-state signed on to the Nagoya Protocol, which therefore, becomes enforceable in the signatory countries. The Nagoya Protocol demands *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*.<sup>8</sup>

One consequence for the construction of the CFI is that it can include adherence to such international conventions as part of its certification.

An active certification system like the proposed CFI can have a strong global impact at relatively low cost and infrastructural needs.

Conceptualised in this way, it became rapidly clear that the terrain of international health research partnerships is vast and largely unstructured, and that providing a framework of ‘fairness’ in many other components of research and innovation partnerships was a high priority for a very different set of stakeholders: not only for governments and research institutions of low and middle income countries but also for private and public research institutions in high-income countries, research sponsors, philanthropies, researchers and research managers everywhere. Seven examples are given on page 16 below.

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<sup>6</sup> <http://www.cohred.org/frc>

<sup>7</sup> <https://www.gov.uk/lambert-toolkit>

<sup>8</sup> <http://www.cbd.int/abs/>

## The proposed COHRED Fairness Index – *in a nutshell*

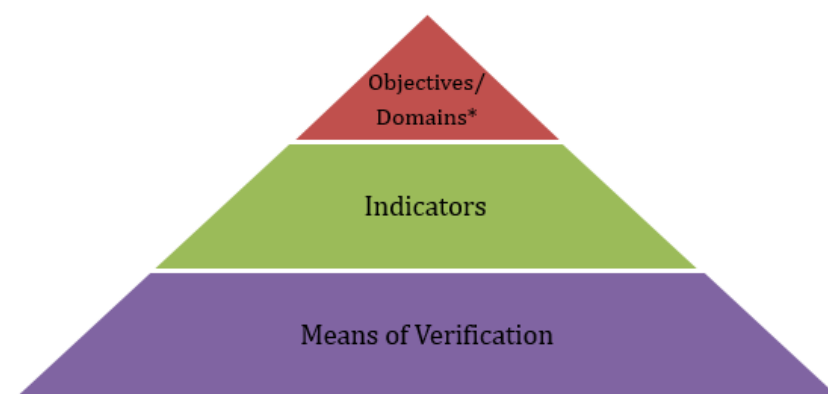
The CFI will:

- Be an actively managed certification system
- Certify the ability to engage in and sustain fair research and innovation partnerships
- Consist of a widely agreed upon measurable set of best practices
- Enable users to gradually improve their own practices
- Use independent verification
- Provide certification – a graded ‘seal of approval’
- Be applicable worldwide
- Be implemented at two levels to start with: assessing availability and use of measures conducive to fair research and innovation partnerships at institutional and national levels
- Explore expansion to certification at project/programme and partnership levels as soon as practicable
- Measure conditions essential to the fairness in research and innovation rather than partnerships themselves – at least at the start
- Be affordable and cost-effective in order to make it accessible to all its stakeholders without undue dependence on third parties

## Building Blocks of the COHRED Fairness Index

In order to shape the final contents of the COHRED Fairness Index, it has to specify the hierarchy of elements or 'building blocks' that, collectively, constitute the CFI in more detail.

Now that the overall aim of the CFI has been clarified – it is essential to be explicit about the 'domains / objectives / or areas' that the CFI should cover if it is to have maximal use and applicability for all stakeholders.



\*Several Objectives/Domains will be discussed.

Figure 4. Domains of the CFI : adapted from ISEAL Emerging Standards – Module 2: Setting Standards<sup>9</sup>

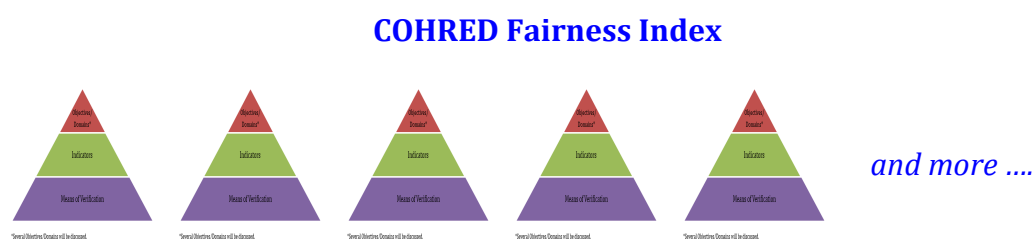


Figure 5. The CFI will need to capture several “Domains” - prioritizing utility to stakeholders, cost-effectiveness, and measurability

<sup>9</sup> <http://www.isealalliance.org/online-community/resources/module-2-setting-standards-0> and <http://www.isealalliance.org/sites/default/files/Standard-Setting-Code-v5.0.pdf>

## Domains the COHRED Fairness Index is likely to include for certification

As we started work on the CFI and began wide consultations with all types of stakeholders in global research and innovation for health, it became clear that there are many other very good reasons why a CFI could be useful. As we heard more opinions, there are at least 7 other major domains where the CFI can have positive impact - each of which may have to find a place within the COHRED Fairness Index.

1. **Domain 1: Balancing Research and Innovation Contracting process:** In 2006, the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) raised the issue of equitable research contracting practice with the World Health Organization's Advisory Committee on Health Research(3). ICDDR,B conducted a survey that found that more than 70% of the contracts were negotiated by principal investigators rather than by their base-institutions, and that more than 85% of the contracts were identified as unclear or difficult to understand by staff who handled the contracts. One result of this work was the development by COHRED of a Fair Research Contracting (FRC) Initiative – [www.cohred.org/frc](http://www.cohred.org/frc).
2. **Domain 2: Valuating contributions (Equal Partnership is not the same as Equal Financial Contribution):** while there is a general wish to describe research and innovation relationships as 'partnerships', this does not imply financial or other equality in power between partners. The same applies to 'co-financing' of research and innovation efforts and funding schemes : a million dollar to a high income country Foundation is not the same as a million dollar to a low or middle income country research and innovation institution. The CFI will need to find a practical definition of how 'equal' is defined and assessed in fair partnerships.
3. **Domain 3: Return On Investment (Responsibility for post-research action):** research and institution sponsors, pharmaceutical companies, large research institutions in high income countries and their collaborators in LMIC would like to have an acceptable standard of what constitutes 'best practice' in ensuring that the outcomes of research and innovation (e.g.: medicines, diagnostics, technologies, etc) developed as a result of research become available and accessible to populations and countries that participated in research. The CFI will need to develop a reasonable standard of responsibility and accountability to all stakeholders, including tax payers and 'beneficiary populations'.
4. **Domain 4: Minimizing Reputational harm (Reputational risk):** not having substantive and transparent guidelines with clear systems of implementation puts all actors in the research and innovation process – especially private sector and research and innovation sponsors – at risk for reputational harm and demands for financial compensation for real or perceived harm. A CFI should be able to significantly reduce risk of reputational harm.
5. **Domain 5: Acceleration of contracts, increased accountability, trust:** negotiating any contract, including for collaborative research and innovation, without competent negotiators on both sides is a recipe for delay, frustration, lack of trust, and even corruption. The CFI should incentivise all sides to invest in growing research and innovation partnerships management capacity and transparency – leading to quicker and better contracts, increasing trust, reduction of financial loss, increased efficiency in partnerships and sustainability of these partnerships – which – in itself is a determinant of efficiency and productivity.



6. **Domain 6: Harmonizing relationships (Aligning different interests of different partners)** – Most successful research and innovation institutions and their staff have world-class expertise and operate in a very competitive environment where excellence and productivity are the main focus. Researchers in such institutions may not realise the extent of the systems that surround them that enables them to become super-focused and highly productive. Countries and institutions on the way to becoming world-class often have other priorities than solving a disease problem. In particular, they may want to become globally competitive, be able to attract people and finance, spin-off companies and create value in their societies. By clarifying different objectives and finding space to meet both output and system goals of all partners, the CFI can be instrumental in changing ad-hoc collaborations that cost much energy to create into long-term, productive partnerships that are easier to maintain.
7. **Domain 7: Preventing ‘collateral damage’ of large research and innovation programmes**: when a given research program ( e.g.: one large clinical trial) diverts the limited human resources of a country towards that program (e.g: nurses or physicians as clinical trial monitors) it is obvious that health research can do more harm than good – particularly to struggling health systems. The CFI could include a measure of how potential partners address this risk to health and health systems.

There are many more domains where a CFI can have positive impact – which is exactly what we intend to find out through this consultation. Please do provide comments and insights into other areas where you feel the CFI should play a role.

## COHRED Fairness Index - adding value to all stakeholders in research and innovation for health

In the construction of the CFI, we are mapping expectations of different potential users of the CFI to understand better how it can create alignment of the objectives of the CFI with the level of assurance that each CFI user will want before engaging with it. The table below gives a summary of this 'map' up to now. Please add where appropriate.

<b>Table 1.</b> <b>Potential BENEFITS OF USING THE COHRED FAIRNESS INDEX</b> <b>TO DIFFERENT STAKEHOLDERS</b>	
If you are a donor	<ol style="list-style-type: none"> <li>1. You will demonstrate respect and value for transparency and openness to public scrutiny of engagements with grant recipients.</li> <li>2. You are thinking local, respecting the priorities of your beneficiaries.</li> <li>3. Wide application of the CFI will lead to improved national priority setting, accountability and institutional research and innovation management capacity.</li> </ol>
If you are grant recipient	<ol style="list-style-type: none"> <li>1. Enhance public profile as a proof to research and innovation sponsors and the public that the utilisation of grants is executed under the code of conduct of the CFI.</li> <li>2. Increase your fundability by building and improving longstanding relationships based on reputation and trust with collaborators.</li> <li>3. Facilitates access to partners and partnerships.</li> <li>4. Better contracting expertise.</li> </ol>
If you are a <b>research and innovation</b> contract organisation or SME in health in a low middle-income country	<ol style="list-style-type: none"> <li>1. Gain leverage to convince local governments and private sector to invest in priority problems.</li> <li>2. Easier to establish and gain access to local resources.</li> <li>3. Access to a practical tool to prove transparency.</li> <li>4. Higher result rate and lower failure rate.</li> <li>5. Gain a competitive edge.</li> <li>6. Provide a proof of books: Proof of fairness, provides validity. Maintain an up-to-date record of practices.</li> </ol>
If you are a low income R&D institution seeking to improve funding track	<ol style="list-style-type: none"> <li>1. Gain partners sensitive to best practices, for example by using FRC, and focus on priorities.</li> <li>2. Increase the benefits sharing and negotiating ability.</li> <li>3. Provides you with incentives to improve institutional capacity for research and innovation management.</li> <li>4. An investment in the future value of the institution.</li> <li>5. Provide assurance to partners/collaborators that the figures and activities shown in contracts are true and equitable.</li> </ol>
If you are a pharmaceutical company	<ol style="list-style-type: none"> <li>1. Decrease reputational risk, increase credibility</li> <li>2. Have a simple tool to improve the social bottom line of your company.</li> <li>3. Provides a guideline that defines limits to the extent of engagement needed in good partnerships.</li> <li>4. Identify and avoid duplication and redundant activities to reduce transaction costs and time wasting.</li> </ol>

If you are a research and innovation sponsor	<ol style="list-style-type: none"> <li>1. Provides a guideline that defines key characteristics of fair and productive partnerships – which you can include in your grant requirements.</li> <li>2. Results in an increased pool of competent research and innovation managers in your partner institutions.</li> <li>3. Reduce potential conflict of interest in partnership with the private sector in funding research and innovation.</li> <li>4. Demonstrate commitment to transparency.</li> </ol>
If you are a ministry of health, science and Technology in low middle-income countries or Research Council	<ol style="list-style-type: none"> <li>1. Have donors and research and innovation sponsors align better with national priorities.</li> <li>2. Research and innovation system building is enhanced.</li> <li>3. Practical tool to support national research and innovation governance.</li> <li>4. Build institutional partnerships and promote moving from personal driven to strategically institutional driven relationships with collaborators.</li> <li>5. Demonstrate that the institution has a strong control environment that sufficiently mitigates potential risks.</li> <li>6. Easier agreement on 'equity' in partnerships.</li> </ol>
If you are an international organisation	<ol style="list-style-type: none"> <li>1. Reduce potential conflict of interest in partnership with the private sector in funding research and innovation.</li> <li>2. Provides a practical and transparent approach to research and innovation engagement for global health.</li> <li>3. Practical tool to exercise global research and innovation stewardship.</li> <li>4. Promote a culture of 'consciousness for equity in partnerships'.</li> </ol>

# Governance & Management

## International Indices - *background*

The three most common types of governance structure for internationally used standards or indexing systems are :

- **Membership based:** Individuals or organisations will have indirect representation in decision-making, e.g. Board of Directors (representation from different sector, interest and geographic scope).
- **Appointed decision-making body:** Members representing the interests of different stakeholders each elected by the 'standard-owner' or by the appointed decision-making body itself.
- **Multiple appointed decision-making body:** A small governance body (strictly operational focusing on 'due diligence' of organisation) and a larger body that is actually responsible for the decisions on the content and features of the Standard/Index System. (Possibly the implementing organisation or a Technical Advisory Board to the implementing organisation).

## COHRED Fairness Index

To advance the global acceptance and use of the COHRED Fairness Index (CFI), a credible and impartial governance structure needs to be put in place.

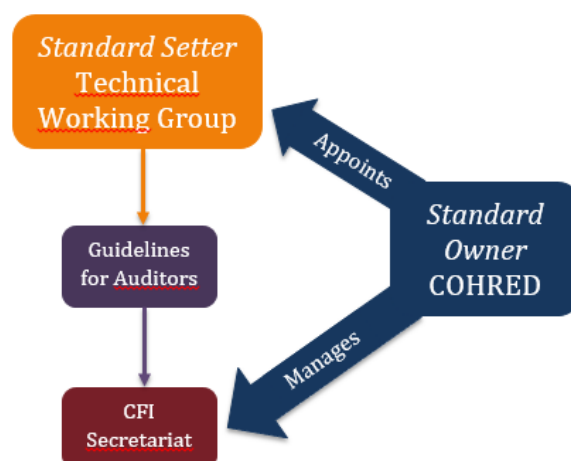


Figure 6. Schematic diagram of the proposed governance structure of the COHRED Fairness Index

**The following key points** have been considered to be essential in proposing an appropriate governance structure for the CFI:

1. **Independence:** the governance structure will probably not differ from other proven governance structures of international standards, but it shall be independent and transparent with an expertise that inspires confidence and confers credibility and legitimacy.
2. **Low cost:** A heavy governance structure will be avoided to 'keep costs down and enable agility'.
3. **Stakeholder representation:** A strong emphasis is given to balance in constituency, gender and geographical representation

In summary:

The '**standard owner**' of the CFI is COHRED i.e. COHRED owns the standard and gives the seal of approval when the standard is met. (*see Operational Model-Appendix II*)

The "**standard setter**" is the multi-stakeholder Technical Advisory Group that operates in terms of standard setting independently of COHRED. COHRED is a member of the TWG like any other stakeholder. This group has the mandate to improve, update, change, and evolve the CFI according to agreed and transparent process.

**The size, composition and *modus operandi* of the TWG are key to its effectiveness and credibility, and will require careful consideration and consultation. Inputs are actively requested from all stakeholders, at this time.**

The Technical Advisory Group is also responsible to outline accreditation guidelines and criteria for independent assessors.

**The proposed organisational home for the CFI is COHRED** – which will have two main areas of responsibility:

1. **COHRED CFI staff:** ensures implementation of the work of the CFI independent of other COHRED work. It concerns 5 major functions:
  - 1.1. Secretariat to the Technical Advisory Group
  - 1.2. Implementation of CFI activities
  - 1.3. Reporting
  - 1.4. Certification
  - 1.5. Financial sustainability and management
2. **COHRED Board:** operational oversight and ensuring due diligence in the way COHRED implements the CFI, as it does for all other COHRED work. The Board does not influence the standards nor the certification process.

## Operational Model

In the case of the COHRED Fairness Index (CFI) – designed, at the start, for implementation at the institutional and national levels - ***we propose a system similar to the model 3 described in the previous section: a combination of self-assessment supplemented by periodic external audit and accreditation of assessors/auditors.*** This should provide a relatively simple and cost-effective, three-step approach that allows for a separation between assessment/audit and certification. A schematic representation of the proposed process is given in Figure 6.

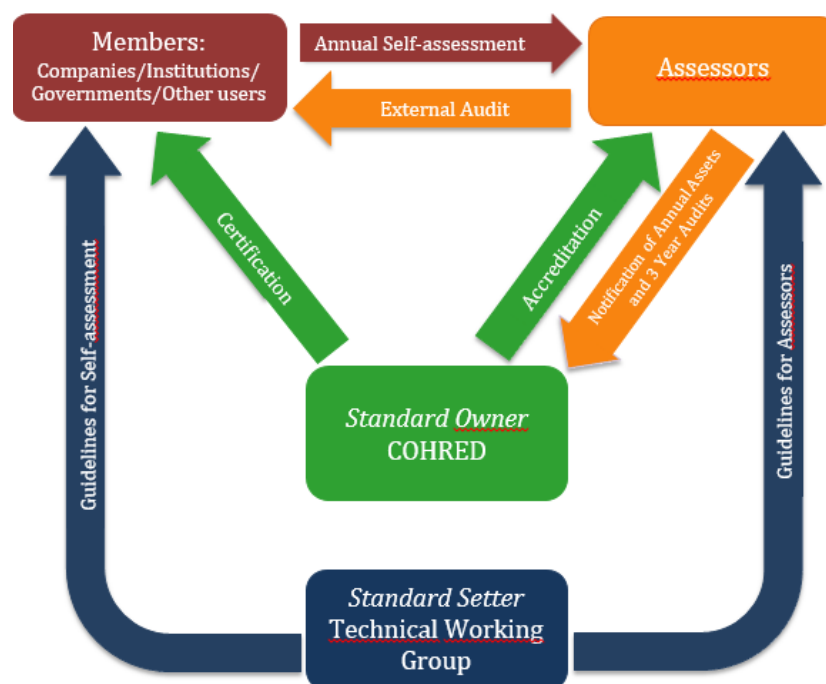


Figure 7. Work Flow design of the operational model of the COHRED Fairness Index

### The Essential Steps Proposed to Operate the CFI are:

1. Reporting through self-assessment on a set of indicators developed by the TWG under the CFI. The reporting is envisaged to be annual: from Member to Assessor, and to their own client-base, for example.
2. A 3-yearly external audit performed by individuals or organisations who are legally and structurally separate from COHRED, who use CFI Standards and Guides developed and maintained in a transparent process managed by Technical Advisory Committee.

3. Accreditation of Assessors/Auditors will be done by COHRED using Accreditation Guides prepared by / approved by the Technical Advisory Committee in a public and transparent manner. COHRED will provide updated listings of assessors/auditors and Members may select the assessor/auditor of their choice. The contracting of the assessors/auditors is left to individual institutions or countries. Selection of auditors may include criteria of cost but also feedback or other services – the determination of which is left to contracting institution or government.

Guidelines to prevent conflict of interest in selection of assessors / auditors will also be prepared.

4. External audit reports are sent to COHRED to complete information needed for certification / re-certification. The role of COHRED will be to verify that Assessors/Auditors adhere to CFI process, guidelines and accreditation requirement. COHRED has no influence on audit outcomes.
5. Constructive feedback from auditors/assessors to institutions, in addition to the audit report, is expected as part of accreditation of assessors/auditors. Assessors/Auditors will also inform COHRED of adequacy of annual self-assessments (or short-falls) and of external audit results.
6. Certification and/or Indication of Corrective Action Requirements will be provided by COHRED, based on timely submitted self-assessments, external audits, and verification of due process by auditors/assessors.

To ensure the CFI works, COHRED's responsibilities include:

7. Preparing Guides and Standards for self-assessment and external audit through the Technical Advisory Group, obtaining global inputs, ensure wide dissemination and use.
8. Preparing Guides and Implementation System for accreditation of assessors and auditors through the Technical Advisory Group, dissemination, maintenance of a public listing of assessors/auditors, and operate a global accreditation system and quality control of this system.
9. Reporting, Awarding Certification Labels or Logos, and monitoring of effective and correct implementation.

**The CFI system is primarily designed to provide a pathway for all stakeholders in health research and innovation partnerships to improve partnership arrangements, effectiveness and outcomes over time.** The CFI is NOT meant to be a 'comparative ranking' system, and definitely not a 'naming and shaming' version of this. The following tools and reporting are proposed to support this operating principle:

**9.1. CFI may decide to use a ‘step-wise’ scoring system – possibly in the following ‘traffic-light’ manner:**

- 9.1.1. *Those with a positive score on 75% of indicators or more and do not score negative on any ‘major’ indicator* will be awarded a GREEN certification valid for a period of 3 years subject to annual submission of self-report.
- 9.1.2. *Those with a positive score of 50 to <75% of indicators and do not score negative on any ‘major’ indicator* will be awarded an ORANGE certification valid for a period of 2 years subject to annual submission of self-report.
- 9.1.3. *Those with a positive score of <50% of indicators and/or score negative on any ‘major’ indicator* will be flagged RED and not awarded the certification. A report with a corrective action needed to achieve the certification is issued by COHRED.

**9.2. Dealing with disagreements:** to deal with discrepancies and interim changes in status quo of users, we propose the following:

- 9.2.1. *In case of substantive changes* (e.g. change in law, merger, change of mission of institution etc.), the institution involved needs to notify COHRED. An assessment will be done to see existing certification needs to be withdrawn, if corrective action needs to be taken, or if renewed self-assessment or external audit is required.
- 9.2.2. *In case of complaints or an expression of disagreement* submitted by any legitimate stakeholder involving a particular certified institution or government, COHRED may require a renewed self-assessment and/or audit even before the normal scheduled assessment or audit is due, or withdraw the certification altogether.

**9.3. Public and Individual Reporting by the COHRED Fairness Index**  
The CFI will focus both on individual and public reporting – through

**9.3.1. Individual Reporting**

- Certification
- Possible supplements to audit reports
- Comments on self-assessment reports

**9.3.2. Public Reporting – periodically / annually**

- Listing of certified users – including Green and Orange label
- Listing of accredited auditors / assessors
- Guidelines, Indicators, Process descriptions
- Monitoring and Evaluation Reports and Analysis: based on member reports, external audits, and ad hoc investigation
- Financial reports and external audits of COHRED

**9.3.3. Public Reporting – on-going**

- Web-based information – updates and real-time information on most of the above
- Newsletter to users to stimulate continuing improvement

**9.4. Training for Assessors/Accreditation – possibly for members:**

Successful implementation of the CFI will be crucially dependent on ability to self-assess and do external evaluations, on the one hand, but also on the ability of members to act on correction reports. It may well be needed to develop training materials or formats if it proves to aid in CFI implementation, through COHRED or in collaboration with partners. At this stage, we have not foreseen this yet.



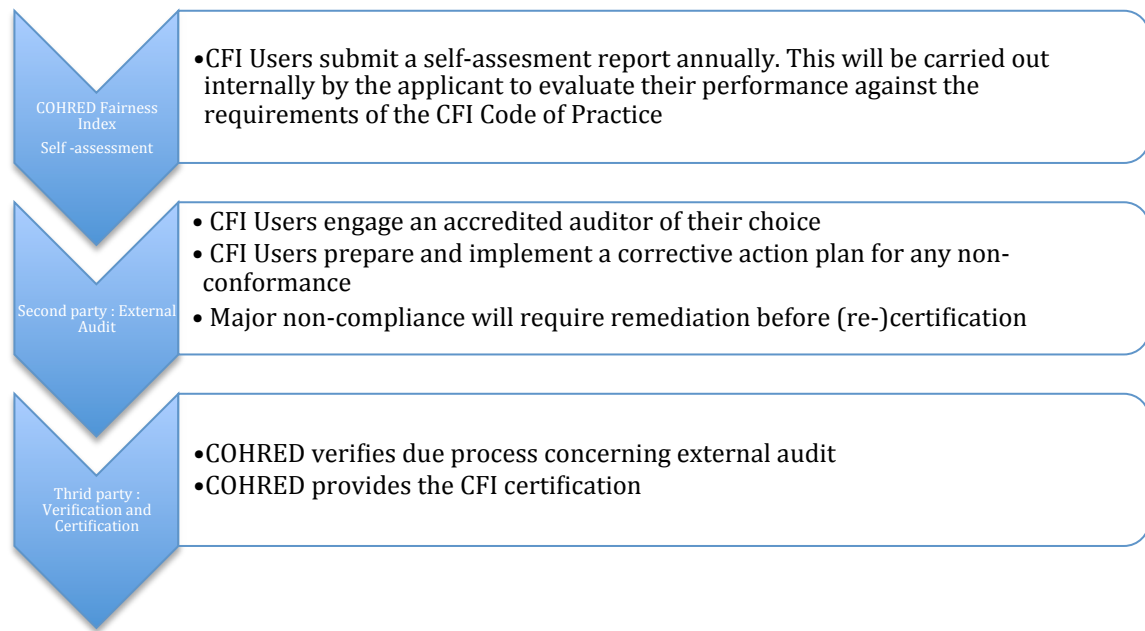


Figure 8. Core of proposed implementation scheme of the COHRED Fairness Index

# Financial Sustainability

**The proposed CFI is designed as a non-profit, financially self-sufficient index system operated within an existing organisational infrastructure to minimize start-up costs.**

Achieving financial sustainability for the CFI has been divided into three phases:

## Phase 1: development – up to October 2015

This is our current phase. The costs are carried by COHRED from its core budget, and are supplemented by contributions from Pfizer, Sanofi and Celgene including an in-kind contribution from the Wellcome Trust. We hope that other sources of funding become available before October to reach a balance between paying stakeholders.

## Phase 2: Start-up – three years: 2016 up to 2018

From October 2015, when the CFI will be activated, we expect a gradual increase in users, including paying users. The exact business model for financial self-sufficiency is being developed currently– but, irrespective of the model, we anticipate it will take 3 years for user derived income to cover costs.

1. To implement the start-up phase and create a core operating unit we estimate that EUR 300,000 per year will be needed for 3 years at the very minimum<sup>10</sup>
2. For credibility reasons, it is essential that the sources of funding are balanced, i.e. funding should not represent one group of stakeholders only.

## Phase 3: Implementation, Improvement, Growth – from 2019 onwards

User derived income should cover cost and future growth. The experiences of other successful and sustainable indices show that maturity is often only reached after 10 years or more.

At this time, we envisage a mixed source of income derived from the following (not necessarily in the order of priority). The low range corresponds to fees charged to users in low middle-income countries. At first sight, the potential for income generation allows the CFI to become self-sufficient and grow gradually after that. We hope and expect that such state can be reached within 3 years.

Magnitude of Annual Contributions needed to make the CFI self-sufficient – *indicative* :

1. **Non-profit institution/organisation membership fees** (approximately EUR 2,500-10,000)
2. **For-profit organisation/corporate/ low middle-income SMEs membership fees** (EUR 5,000-20,000)
3. **National membership fees** (EUR 7,000-50,000)
4. **Assessors Licence fees** (EUR 1,500 – 3,000 for individuals and 10,000 – 25,000 for corporate)

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<sup>10</sup> On the one hand, we want to make the CFI cost-effective and accessible to all its future users.. On the other hand, feedback received during Global Consultation- I, suggested that we are vastly underestimating the cost of running the CFI. What are your comments?

5. **Research and innovation sponsors and research and innovation funders** (EUR 10,000-50,000)
6. **Philanthropy and impact investors** (EUR 10,000-50,000)
7. **Fourth party funding** for institutions that cannot afford
8. **Additional sources** to be developed

At this time, we can not be very specific as our market survey and understanding of the business plan of the CFI is far from complete. Following the first Global Consultation and the April High-Level Meeting, we will be able to be far more detailed in building a solid business plan for the CFI.

Until then, we propose that the following funding streams will be at the heart of the financial sustainability of the CFI – see Figure 8 below.

1. **Annual membership fees for users** – inclusive of the certification.
2. **Annual auditor accreditation fees.**
3. **Periodic external audit fees** paid by Users directly to accredited auditors.
4. **Donors or sponsors contributions** for institutions that cannot cover CFI costs themselves (for example, as part of grant awarding to institutions, the funder may demand that the grantee institutions are CFI compliant) or pay for specific expansions or applications of the CFI that can not be funded from regular income.
5. **Additional sources** may be developed as the system advances.

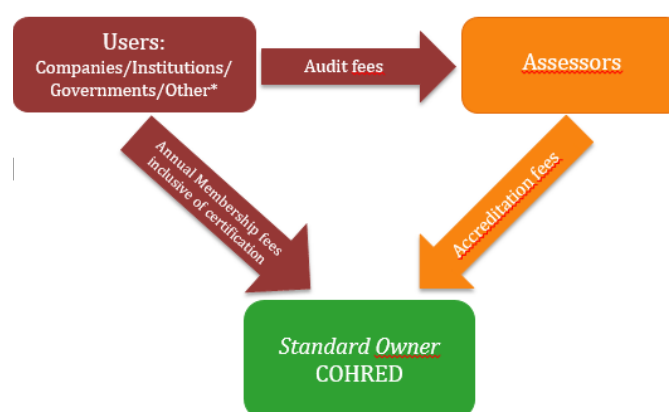


Figure 9. Schematic representation of financing the implementation of the COHRED Fairness Index

In preparing a business plan, we considered who will be ‘critical users’ – and who will be ‘critical payers’ to see how much overlap there is. See table 2 below.

**Table 2**  
**“Critical Users” and “Critical Payers” of the CFI**  
*– for consideration and improvement*

	Critical User	Category	Critical Payers +/++/+++
1	Research and Innovation / Academic Organisations in LMICs	Non-profit institution/organisation	+++
2	LMIC Governments Health, STI, Education, Finance	National membership	+++
3	Pharmaceutical Industry (And related industry: CROs, Medical Technology, Health & Beauty producers)	For-profit organisation/corporate/ low middle-income SMES	+++
4	Global non-profits, PPPs, international research and innovation collaborators	Non-profit institution/organisation	++
5	Bilateral donors / HIC Governments of Development Cooperation, Foreign Affairs	Research and innovation sponsors and research and innovation funders	++
6	Philanthropies in this area, including disease specific foundations	Philanthropy and impact investors	++
7	International Research and Innovation Sponsors	Research and innovation sponsors and research and innovation funders	+++
8	HIC research and innovation institutions, universities	Non-profit institution/organisation	+++
9	International Organisations	Fourth party funding for institutions that cannot afford	+
10	Patient (Safety) Organisations	Non-profit institution/organisation	-
11	Media / scientific and public press etc.	Fourth party funding for institutions that cannot afford	-
12	Research and innovation start-ups (non-profit, for profit)	For-profit organisation/corporate/ low middle-income SMEs	+
13	Others	Additional sources	-

## Branding Strategy COHRED Fairness Index

Until there is more clarity about the CFI, its users and payers, we can not focus on branding of the COHRED Fairness Index (CFI). Following the Global Consultation (1) and the London High-Level Meeting in April, branding and marketing will become a priority.

## **Label and Trademark for COHRED Fairness Index**

As part of the consultation with the COHRED Board and the COHRED Fairness Index (CFI) Technical Working Group, it was decided to pursue a trademark in Switzerland for the CFI. COHRED Fairness Index was filed for trademark registration in Switzerland (Swiss Trademark n° 664310). This allows CFI to be associated to the annotation, <sup>™</sup> providing it a strong protection at the national level. For further protection at the international level, the Madrid System for international registration of trademarks (Madrid Protocol) is currently under consideration.

## **Monitoring and Evaluation**

To demonstrate the practical impacts of the COHRED Fairness Index (CFI), it is essential to determine what improvements have been achieved within a three-year (short-term) or a 10 year (long-term) span. A monitoring and evaluation (M&E) program will be an important aspect of the CFI to determine the changes in international collaborative research and innovation in health that have occurred over time as a result of cumulative behavioural and etiquette changes in the potential users of the CFI.

At this time, we have noted the urgency to develop a comprehensive M&E system, but realise also that the M&E system is intimately linked to decisions about the CFI Goal Statement, Objectives/Domains and Indicators – i.e. the very topics of this phase of consultation. Once these are clear, and we have had time to develop and agree on indicators and means of verification, we anticipate that short-term evaluation would link to the use of the CFI. In the medium- and long-term, a focus on outcomes and impact on practices of stakeholders will be possible. More downstream impact measure may well be possible to create, but we decided not to spend time on this until there is agreement on the goal and domains of the CFI..

### Short term M&E

- Number / increase of users
- Number / increase of payers
- Increase of certifications per year
- Number of attendees at CFI consultation events
- Number of citations of the CFI
- Financial results

### Medium and long term

- Number of orange and green certifications awarded and those moving from one to the other
- Quantification of the changes in the indicators that measure the achievement of the objectives and principles of the CFI (See pages 23-24). This is the basic ‘outcome’ framework for the CFI.
- Work still needs to happen to find suitable long-term impact measures.

## How to Engage the CFI development

### 1. Comment on this Document

It may well take 3-5 years to set and begin operating this Index, and many more years to mature the concept and its implementation but this will not stop us from beginning and advancing the process. A global participation of stakeholders at this early stage is key to ensuring it will serve your purposes as well as those of others – that you are represented as well as others.

**Global Consultation 1 – i.e. this document – will take place between 22 January and 27 March 2015.** After that, we will be preparing a new document based on all the inputs received. Please contact us by mail or phone, or leave a comment on this document on our website using the following contact details:

E-mail: [musolino@cohred.org](mailto:musolino@cohred.org)  
Telephone: + 41 22 591 89 00  
Website: <http://cfi.cohred.org>

### 2. Endorse the COHRED Fairness Index - now

This development stage is a sensitive period and depends on scarce funding, a small but committed group of people, and – most importantly – on the clear expression of interest of future users.

**You can help this effort tremendously by making your support for the CFI known through an endorsement. Endorse the need for and process of development of the CFI, without committing in any way – at this time – to the final product nor to future use.**

The CFI needs it, to get CREDIBILITY, LEGITIMACY and RECOGNITION. The CFI website will carry the names (and logo's) of institutions and names and affiliations of individuals on the CFI website – if you agree.

In Appendix I, we have included two Template letters : one for Institutional and one for Individual endorsement of the CFI. You are free to modify these to suit your circumstances better.

We provide a possibility of endorsement on the COHRED Fairness Index website as well <http://cfi.cohred.org> or by directly contacting [musolino@cohred.org](mailto:musolino@cohred.org).

### 3. Support Us

Especially in the first 3 years, we need start-up funding and it needs to come from a multitude of potential Users to enhance its credibility. Even small contributions can help us achieve the targets for getting the CFI off the ground. A budget is provided in the section on “Achieving Financial Sustainability” on Page 32.

If you want to make a financial contribution – please contact Najia Musolino directly on [musolino@cohred.org](mailto:musolino@cohred.org)

## Further reading

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# APPENDIX I

Endorsement letter on behalf of an institution:

**USE YOUR INSTITUTION'S LETTERHEAD, please**

**TO COHRED**

## **ENDORSEMENT FOR THE COHRED FAIRNESS INDEX (CFI)**

In our capacity as the....., we write to express our support for the development of the COHRED Fairness Index (CFI).

**We understand and support the COHRED Fairness Index (*for ethical and equitable research and innovation collaborations for health*), which is being developed through global consultation of all stakeholders – to create a certification system that promotes fair practices, transparency and accountability in research and innovation partnerships for global health.**

**In doing so, the CFI hopes to contribute substantially to global health by improving research and innovation partnerships, financing, benefit sharing, institutional and national research and innovation management and governance, infrastructure, and more – especially in low and middle income countries and populations.**

Accordingly, we are pleased to endorse the need for the COHRED Fairness Index.

We understand that by endorsing the COHRED Fairness Index, we are not committed to approve the final Index nor to become a User. Endorsement also does not commit us to make any financial contribution – even though we may decide to do so to advance or accelerate its development.

We agree that the official logo of ..... can be used as a symbol of endorsement of the CFI on any relevant documentation (advocacy material, web portal, meeting presentations) produced related to the CFI.

Finally, we understand that we can cancel our endorsement at any time by informing COHRED in writing of our decision to do so.

Signature  
Position  
Institution  
Place  
Date



Endorsement letter for individual:
------------------------------------

**PLEASE USE YOUR OWN PERSONAL LETTERHEAD, if available**

**TO COHRED**

**ENDORSEMENT FOR THE COHRED FAIRNESS INDEX (CFI)**

In my personal capacity, I want to express my support for the development of the COHRED Fairness Index (CFI).

**I understand and support the COHRED Fairness Index (*for ethical and equitable research and innovation collaborations for health*), which is being developed through global consultation of all stakeholders – to create a certification system that promotes fair practices, transparency and accountability in research and innovation partnerships for global health.**

**In doing so, the CFI hopes to contribute substantially to global health by improving research and innovation partnerships, financing, benefit sharing, institutional and national research and innovation management and governance, infrastructure, and more – especially in low and middle income countries and populations.**

Accordingly, I am pleased to endorse the need for the COHRED Fairness Index.

I understand that by endorsing the COHRED Fairness Index, I am not committed to approve the final Index nor to become a User. Endorsement also does not commit me to make any financial contribution – even though I may decide to do so to advance or accelerate its development.

I agree that my name can be used as a symbol of endorsement of the CFI on any relevant documentation (advocacy material, web portal, meeting presentations) produced related to the CFI.

Finally, I understand that I can cancel our endorsement at any time by informing COHRED in writing of our decision to do so.

Signature :

Position (*optional – but preferable*)

Institution (*optional – but preferable*)

Place

Date

## APPENDIX II – Background information to the various sections of this report

### Consultation and Decision-Making

#### Values Process

While we have given significant importance to stakeholder input for designing the COHRED Fairness Index, great attention has also been given to the ground breaking work done by the ISEAL Alliance to develop the understanding of building robust index and certification systems that focus on environmental sustainability.<sup>11</sup>

In the preparation of this document we have relied extensively on the ISEAL Credibility Principles<sup>12</sup> in particular and adapted these where appropriate. In addition, we consulted 65 other certification systems and indices that seem to have relevance to the development of the CFI (*see the CFI website <http://cfi.cohred.org>*)

#### Timetable

The development of the COHRED Fairness Index (CFI) includes a sequential process of multi-stakeholder consultation and reporting. The following flow-chart describes the process from the inception of the CFI until its expected launch in October 2015.

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<sup>11</sup> <http://www.isealalliance.org>

<sup>12</sup> Principles for Credible and Effective Sustainability Standards Systems, ISEAL Alliance.



Figure A. Timelines of the work plan for the development of the COHRED Fairness Index

## Stakeholder Consultation

An index can only be as good as the added value that it offers to all its stakeholders. To ensure optimal value for all partners in collaborative research and innovation for health, we are committed to a very open process of consultation and decision-making.

The development of the CFI is the result of a multi-sector consultation approach involving a Technical Working Group (TWG) with representative key stakeholders from both categories including NGOs, international organizations, philanthropies, donors, the public and private sector as well as academic institutions. Using rigorous methodology, these key stakeholders in global research and innovation propose CFI as an important tool that highlights new opportunities for fair and equitable partnerships in resource limited settings. With a size of 28 members, the TWG has been built to represent a wide spectrum of constituencies with close attention to balance in gender and geographical representation. The stakeholders were engaged for consultation through 5 rounds of consultation (electronic surveys) as well as interviews (by phone or in person). The stakeholders engaged during the consultation period defined the preliminary features of the CFI. Details on the membership and constitution of the TWG can be found on <http://cfi.cohred.org/technical-working-group/>.

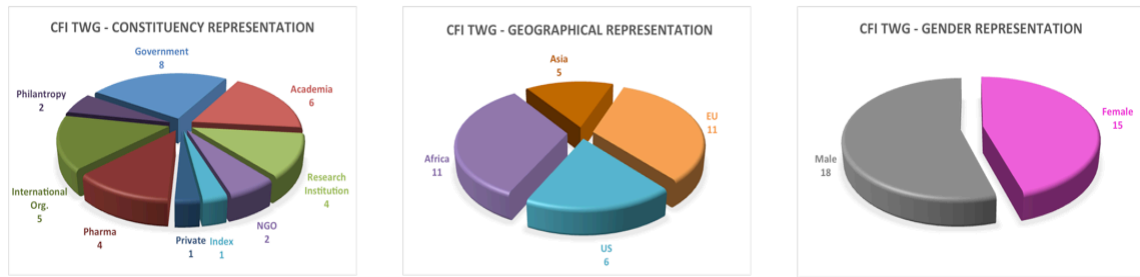


Figure B. CFI Technical Working Group. With a size of 33 members, the Technical Working Group has been built to represent a wide spectrum of constituencies with close attention to balance in gender and geographical representation.

**Activities undertaken thus far for maximum engagement of all stakeholders:**

1. Posting of this document (in downloadable and on-screen, interactive format) to enable a worldwide dissemination and review.
2. Crosslinks to CFI website through interested organisations (IAMP, EQUIDAD, TDR/WHO, Pasteur Institute)
3. Use of workshops and conferences/colloquia in which COHRED is involved
4. Twitter and Facebook campaigns
5. Campaign to get early endorsements – of the principle and process (see further in this document)

## Setting Standards

### ISEAL Principles

This section has been adapted from work done by the ISEAL Alliance.<sup>13</sup> The ISEAL Alliance, a global membership association for sustainability standards, proposes ten principles of credibility as the nucleus around which standards should be built. The ISEAL Alliance encourages use and adaptation of these principles to suit specific standards, such as the CFI, rather than using them as compliance guidelines for the development of any Standard.

The 10 ISEAL Credibility principles are:<sup>14</sup>

1. (Environmental) Sustainability
2. Improvement
3. Relevance
4. Rigour
5. Engagement
6. Impartiality
7. Transparency
8. Accessibility
9. Truthfulness
10. Efficiency

Please see the ISEAL publication on Credibility Principles for details. We found all except the first one to be of direct relevance to the construction of the CFI, and have replaced '(environmental) sustainability' with 'operational sustainability'.

### Operation of a Standard

#### **New or existing standards?**

The CFI will consider existing guides, tools and international conventions related to research and innovation and take from it what is relevant for the CFI<sup>15</sup>. In addition, where there are no guides, or clear gaps in existing guides, the CFI will design new standards and best practices. Given that there are no existing global certification systems specifically designed to assess fairness in research and innovation partnerships, it is likely that the TWG will have to design many new standards, indicators, best practices in several domains.

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<sup>13</sup> ISEAL Alliance – [www.isealalliance.org](http://www.isealalliance.org)

<sup>14</sup> <http://www.isealalliance.org/our-work/defining-credibility/credibility-principles>

<sup>15</sup> For example : KFPE, ICH-GCP, UNAIDS, CIOMS, Nagoya Protocol, Global Innovation Index - WIPO, WHO , ESSENCE Good practice document, Declaration of Helsinki, and more)

## An 'Index' or a 'System'?

An 'Index' can be a tool that is published for use – a type of 'best practice' consensus without the backing of a 'system' of measurement, verification or certification.

**The CFI is proposed as a 'system'** – including indicator and standard development over time, provision of index tools for self-assessment, followed by a process of verification and certification. Effective implementation will be a process that will take time to develop, and needs a complement of staff and an organisation behind it for improvement, validation, communication and certification.

## Voluntary or externally monitored or both?

Standards can be made available for voluntary use, implementation and reporting. Or a system for measurement, reporting and certification is set up outside the organisations using the index. Or, there is a combination of both.

The CFI is proposed as a mixed model – with a strong component of self-assessment to reduce costs and encourage gradual improvement – complemented by periodic external verification and certification.

There are five ways of increasing intensity to implement 'fairness in partnerships':

1. Raising **Awareness** : Several peer review publications have reported on 'fairness' in partnerships.
  - **e.g. Anthony Costello, Alimuddin Zumla, 2000; Miriam Shuchman et al. 2014, Frank Anderson et al., 2014;**
2. Establishing **principles of best practice** : Voluntary guidelines with implementation dependent on the goodwill of the institutions or individuals.
  - **e.g. KFPE : 11 principles, 7 questions, CIOMS, The Elmina Declaration on Partnerships to address Human Resources for Health**
3. Creating **practical tools** : COHRED offers a set of technical guidance notes and a booklet providing a series of tips on improving negotiation outcomes
  - **e.g. Fair Research Contracting (FRC)**
4. Actively managed **certification system**
  - **e.g. the COHRED Fairness Index**
5. Generating **legal obligation** :
  - **e.g. the Nagoya Protocol : For better legal certainty**

## Operational Model – Index Systems in General

### Operational models

In addition to “what an index measures”, it key to define “how it will do so, and how it will report”. There seem to be four operational models in common use:

1. **Guidelines for voluntary implementation** (*such as the KFPE principles<sup>16</sup>*)
2. **Self-assessment only** (*Good Weave International<sup>17</sup>*)
3. **Self-assessment supplemented by external audit and an accreditation scheme** (*such as well known index systems like the Forestry Stewardship Council <sup>18</sup>, Better Cotton Initiative <sup>19</sup>, Global Reporting Initiative<sup>20</sup>, etc.)*)
4. **External ranking and publishing**
  - a. **Comparative ranking** (*e.g. for responsible investment e.g. Vigeo<sup>21</sup>, Covalence Ethical Quote<sup>22</sup> or for ‘big pharma’ contribution to increase access to medicines e.g. the Access to Medicines Index<sup>23</sup>*)
  - b. **Ranking with ‘naming and shaming’** (*Berne Declaration<sup>24</sup>*)

As we indicate below, it is proposed that **the CFI uses general scheme 3** : a combination of self-assessment supplemented with external audit and an accreditation scheme for auditors / assessors.

We note that “self-assessment” has limitations in evaluating partnerships. By definition, it represents only one side of the partnership. As the CFI is focusing on partnership arrangements, we may decide to widen the concept of “self-assessment” to include all partners. This limitation may have special relevance to ‘project certification’ and possibly less or not at all to use of the CFI at institutional or national levels.

What the CFI does need to include is a transparent manner to deal with diverging opinions between partners. Perhaps this can take the form of a system to object to certification to the certifying body (COHRED) which could then request a renewed self-assessment or a renewed external audit.

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<sup>16</sup> [http://www.naturalsciences.ch/organisations/kfpe/11\\_principles\\_7\\_questions](http://www.naturalsciences.ch/organisations/kfpe/11_principles_7_questions)

<sup>17</sup> <http://www.goodweave.org/home.php>

<sup>18</sup> <https://ic.fsc.org>

<sup>19</sup> <http://bettercotton.org>

<sup>20</sup> <https://www.globalreporting.org/Pages/default.aspx>

<sup>21</sup> <http://www.vigeo.com>

<sup>22</sup> <http://www.ethicalquote.com>

<sup>23</sup> <http://www.accessmedicineindex.org>

<sup>24</sup> <https://www.bernedclaration.ch>

## Scoring Systems

There are, generally, three scoring types in use:

1. **Percentage based scoring:** *attainment of a percentage threshold defines compliance.*
2. **Pass or fail score:** *Non-compliance is divided into major and minor categories, each with a defined pass / fail level for its indicators.*
3. **Stepwise scoring:** *such as a “Traffic Light” system with red, yellow, green practices, including an improvement scheme over a period of time. This usually includes the requirement of conformity with minimum scores for indicators in the initial certification phase followed by further improvement over specified periods.*

*Example: Applicants with advanced level (green) score are awarded the Standard’s seal of approval for 5 years. Applicants with intermediate level score (yellow) are awarded the Standard’s seal of approval for 3 years. Applicants with unsatisfactory score (red) are awarded the Standard’s seal of approval for 1 year followed by an obligatory second round of audit and certification.*

## Reporting and Certification

Reporting is a key component of most operational models. In the most limited application, reporting remains internal and the guidelines serve as an aspirational goal relying on the goodwill of the individual or the institution. At the other end of the spectrum is full public reporting of key information for the sake of transparency and accountability.

Certification labelling is one example of public reporting. Other forms include newsletters, press release, annual reports, monographs, web-site information, social media use and advertising.

## Complexity of Operating an Index

We have studied well over 75 index systems which we thought appropriate to the construction of the CFI. The organisation of these varies from the very simple to very complex, with clear implications for cost and human resources, and therefore, for financial sustainability.

At its simplest, the certifying organisation (‘standard owner’) and the auditors are parts of the same organisation that work independently, a regular practice in financial audit companies. At the other end, the ‘standard owner’ may be different from the certification organisation, which may be different from auditors, which may be different from the organisation accrediting the auditors. In other words, all parts of the process may be outsourced to specialist agencies except the awarding of the “seal of approval” – which remains the domain of the ‘standard owner’.

The clear message in relation to designing an effective COHRED Fairness Index is to create a pragmatic solution that can be performed credibly, at minimal costs, and be set up for future expansion.



## Financial Sustainability – Index Systems in General

### Financial sustainability

While it is common practice to rely on grants-in-aid for the development and start-up costs of any Index, it is crucial to determine a business model that will allow the Index system to achieve self-sufficiency in the shortest possible time early on in the Index development.

We have found many ways in which existing international standards achieve financial self-sufficiency or even make profit if they are designed to serve that purpose. As is well known, there are many businesses and organisations whose core business is certification and accreditation.

Each method or combination of methods will have its particular advantages, disadvantages and potentials for conflict of interest that need to be countered. A major additional factor to consider is that reduction or elimination of disadvantages and potential conflicts of interest is likely to increase complexity and costs of the system – to the extent that some key stakeholders will no longer be able to be (full) users.

A non-exhaustive list of the most common practices is given to help deliberation on what would be best for use in the CFI :

#### **In-cash contributions:**

1. Donations, charitable **grants**
2. Individual/institutional/organisational **membership**
3. **Subscription** service
4. **User fees**
5. **Sponsorship and partnerships**
6. **Fourth party funding:** Bodies along the value chain that will benefit from entities having received certification may subsidise the costs of such audit and certification to improve their own inputs
7. Assessors/Auditors: **Licence fees**
8. **Consultancy services** to meet Index standards
9. **Sales** of Index related material

#### **In-kind contributions:**

1. **Media sponsorship** program for raising awareness
2. **Pro-bono support** from partners to improve awareness and recognition of the CFI label/logo

## “Critical Users and Critical Payers”

To be able to design a sustainable financing system, an Index system will need to have a sharp analysis of who will be the “critical users” and who will be the “critical payers”.

User segmentation is necessary, as any Index system will have different values and benefits for different users. A clear understanding of who the users and who the payers are and what their particular interests are in the CFI is crucial to ensure that the content of the Index is responsive. It is also key to determining the business model and in deciding who should be the priority participants in the continued updating of the Index, for example.

The segmentation may include users both from high, middle or low income countries; from Non Governmental Organisations (NGOs) and Civil Society Organizations (CSOs); investors; donors; capacity building organisations; government organizations; international organizations; researchers and academic institutions; patients or healthcare professionals organisations; corporations; Small and Medium-Sized Enterprises (SMEs); Public Private Partnerships (PPPs) and Product Development Partnerships (PDPs), or any other stratification that makes sense – only limited by the need to reduce complexity and costs of implementation.

“Critical Payers” are not necessarily the same as “Critical Users” – especially not in situations like the CFI where an Index Systems is intended to help reduce capacity gaps.

*For example, a low income-country institution may not be able to cover the full cost of an audit. In this case, the System should still be able to provide an audit at a loss to this particular institution in question but be able to compensate from other sources.*

## Branding Strategy for Index Systems

Non-profit organisations often do not think in terms of branding. However, it is clear from successful International Standards that an explicit branding, labelling and also trademarking can be crucial for success and development of the Index even at an early stage.

## Label and Trademark

Misuse of certification and labelling – especially of those with global impact – is not uncommon. Different modes of protection are available such as patents, trademark or copyright to assure appropriate use of the Index logo/label.