



Beyond Animal Testing
INDEX

Supplementary Material 1

BATI Methodology- Domains and Themes

A. Management and Stakeholders

This domain examines the governance system and management structures of the organisation as well as the objectives and strategies set by the organisation for augmenting conscientiousness of animal testing and stimulating innovation in research. It captures the board of directors, different levels of management and various committees. Additionally, this domain will capture whether the organisation has selected stakeholders relevant to the BATI and whether it actively engages with these stakeholders. The domain Management and Stakeholders is the foundation upon which the principles of the index can be further implemented throughout the whole organisation.

Themes

The index has divided the domain Management and Stakeholders into 5 main themes: governance, strategy, ethical committees, and animal welfare body, managing for Index-related outcomes and stakeholder engagement.

Governance (indicators: A.I.1)

The Index regards governance as the structures and people that form the governing body of the organisation, including higher levels of management and the board of directors. It strongly believes that the transition to animal free innovation should be discussed and considered throughout the entire organisation, including at the highest levels of the organisation, to encourage lower levels to adopt the same mind-set and principles. The board of directors is the highest level of authority in the organisation and therefore the very first level at which the TPI and 3Rs principles should be implemented. The organisation should thus assign board-level responsibility and accountability for animal testing and innovative research as well as lower-level responsibility and accountability on various high levels of management.

Strategy (indicators: A.I.2)

The Index regards strategy as the implementation of the TPI and 3Rs principles within the organisation's main policy and strategy. Aligning the principles with the core of the organisation theoretically secures an animal-friendly and innovation-stimulating workspace. Making a policy does not however ensure that the policy is implemented. Therefore, the organisation should set objectives that contribute to the aim of the Index in their main policy and strategy, justify them with a strong rationale and align them with processes and strategies to ensure implementation.

Ethical committee and animal welfare body (indicators: A.I.3, A.I.4)

Each organisation doing animal testing is required by law to have their own internal animal welfare body in place, as well as either their own internal ethical evaluation committee or access to an external ethical evaluation committee. These committees are known in The Netherlands as the 'Instantie voor Dierenwelzijn (IvD)' (Animal Welfare Body) and the 'DierExperimentenCommissie (DEC)' respectively. The Index investigates how organisations are supporting these two committees and whether these committees do more than they are legally required. For optimal use, the organisation should not only recruit the best (people for the) DEC and IvD, but also create a working environment in which both committees can perform to the best of their ability.

Managing for Index-related outcomes (indicators: A.II.1, A.III.1, A.III.2)

The Index regards managing for Index-related outcomes as the monitoring and regulation of newly implemented processes and strategies to ensure these are translated into positive outcomes. Ideas for implementing the TPI and 3Rs -principles within or outside of the organisation can after all look good on paper but may not work in practice. Hence, the organisation should have a performance management system to manage for Index-related outcomes and address undesirable outcomes adequately.

Stakeholder engagement (indicators: A.III.3)

Stakeholders can be a valuable addition to the organisation if they are included in the decision-making process. They will represent different areas of expertise, making them expert advisors on various subject matters including the transition to animal-free innovation. When stakeholders are engaged in a strategic way, it will allow for dialogue and knowledge sharing, creating the ability to incorporate stakeholders' perspectives and needs in the organisation's objectives, policies, and strategies. This will ultimately lead to improvement within and outside of the organisation. Organisations should therefore actively engage with stakeholders and incorporate stakeholder perspectives into Index-related strategies and decision making.

B. Research and Development

This domain examines the Research and Development department of the organisation. Research and development, often abbreviated as R&D, is the process of developing and inventing new knowledge, products or procedures through conducting studies. The R&D department is an important branch of an academic medical centre. Academic medical centres usually organise R&D into specific research areas, also called research profiles, such as 'cancer' and 'immunity and infection'. Research projects are conducted within one or more of these research areas to assure the highest level of cross-border expertise. The cooperation between different areas of expertise will allow new insights to be formed and better ways of conducting research to be found.

Themes

The index has divided Research & Development into 4 main themes, which are quality standards, research innovation, research practice and collaborative R&D and data sharing.

Quality standards (indicators: B.I.1, B.III.1)

The Index regards quality standards as the standards by which the animals are treated throughout their lives. The formulation of and adherence to quality standards is of great importance for assuring proper handling of the animals and limiting discomfort. The quality standards, as composed by the organisation, should be in line with '*The Netherlands Code of Conduct for Scientific Practice*', '*The European Code of Conduct for Research Integrity*', and quality standards and best practices common to laboratory animal science. Organisations will be rewarded for having better formulated or expanded quality practice in comparison with the aforementioned standards and guidance.

Development and Use of Animal Free Research Models (indicators: B.I.2, B.III.2, B.III.3)

The Index regards research innovation as R&D that leads to the development or adaption of Index-related inventions within specific research areas. Most animal free research models are not set up to replace animal testing, but rather to find a model better suited to answer the scientific question. Thus, it is beneficial for both animal welfare and science to develop and implement new approach methodologies. The organisation should therefore stimulate research innovations in any way possible with the goal to accelerate the transition to animal-free innovation. The organisation should stimulate this research practice and ensure that it is facilitated. In addition, the organisation should take away barriers such as costs.

Collaborative R&D and data sharing (indicators: B.I.3, B.II.1)

The Index regards as the standard 'open science' and essentially the publication of all results of credible experiments irrespective of the outcome. At the present time, studies with so called negative results are often not published, with the possibility that studies are repeated where it could have been avoided. This leads to more animals being used on research projects that will not yield positive results. Organisation should attempt to publish all results, regardless of whether the outcome is positive or negative.

C. Education and Training

Education and Training, or Capacity Building, are a vital part of any research institute. Capacity is defined by the United Nations as “*the ability of individuals, institutions and societies to perform functions, solve problems and set and achieve objectives in a sustainable manner*”. Capacity building, also called capacity development, is the process by which an organisation obtains, improves, and retains this capacity.

Themes

The Index has divided Capacity Building into 5 main themes: initial education, continuing professional development, training need assessment, awareness, and external education.

Initial education (indicators: C.I.1, C.III.1)

The Index defines initial education as the education needed for the development of (basic) qualifications relevant or specific for the role. During this phase, the knowledge and skills levels of the student or employee increases from 0% to 100%. Specifically, the Index will assess if the learning outcomes and the curriculum sufficiently cover the transition to animal-free innovations and new approach methodologies.

Continuing professional development (indicators: C.III.2)

Continuing professional development (CPD) is defined by the Index as the education needed for both the retaining of existing knowledge and skills and the acquisition of newly emerged knowledge and skills. CPD intends to keep the knowledge and skill level of the employee at 100%, even when new techniques are implemented as new standards. Specifically, the Index will assess if the CPD education provided is sufficient for maintaining and improving Index-related skills and knowledge.

Training need assessment (indicators: C.I.2)

In addition to CPD, the organisation should actively assess if specific employees or departments have a lack of knowledge or skill, better defined as a knowledge or skill gap or a training need. This assures a fully competent staff and optimal performance of this staff. Specifically, the Index will look at training needs regarding the transition to animal-free innovations.

Awareness (indicators: C.I.3, C.II.1, C.III.3)

The awareness of internal and external staff and personnel, stakeholders and the public at large, as well as political and global awareness are important. Making people aware of new developments in animal testing and the transition to animal-free innovations will fuel discussion and will therefore lead to acceleration of the transition.

External education (indicators: C.III.4)

With respect to increasing awareness outside of the organisation, an effort should be made towards building the capacity of other organisations through the provision of TPI education. The organisation could share its TPI acquired knowledge with third parties. In this process, the organisation should have an active approach, actively trying to find organisations that want to receive or exchange TPI-related knowledge.

D. Investments & Grants

Through investments and grants a medical academic centre can promote or support research of their choosing. In the same way, the organisation can allocate resources to to 3R research. This area of the index will analyse the institute's policy and expenditures by comparing general investment and grant efforts with investments and grants relevant to the transition to animal free innovations and development and implementation of new approach methodologies.

Themes

The Index has divided investments and grants into 2 main themes: investments and grants.

Investments (indicators: D.II.1, D.III.1)

This theme is focused on the financial support for R&D, as well as the financial expenses related to facilities and facilities relevant to the focus areas of the index. In addition, the Index assesses how the organisation monitors and regulates the deliverables of these investments. The Index regards investments as a means to supporting and implementing transition to animal-free innovation. Investments can be divided into two subtypes: financial support for '3Rs' research projects, and the capital expenditure in utilities and facilities. The Index believes that investments are a way of ensuring continuous innovation in research.

Grants (indicators: D.III.2)

This theme focusses on the acquired grants for (research) projects relevant to the focus areas of the index. The Index believes that grants are a way for the institute to promote and support research relevant to the focus areas of the Index. Granting money or resources to innovative initiatives shows commitment to the transition to animal-free innovation.

E. IP management

Intellectual property, often abbreviated as IP, is a term used to define all property that includes creations of the human intelligence. IP includes trademarks, copyrights, patents, and various other types of rights. The main purpose of IP law is to encourage creation of a large diversity of intellectual goods. For this Index, we will focus on patents, licensing, and open access.

Themes

The Index has divided IP management into 3 main themes, which are patents, licensing, and partnerships.

Patents (indicators: E.II.1)

A patent is a type of exclusive right to use an invention for a set period which is granted to an inventor. Related to the Index, this means that an invention is disclosed to the public, but no other parties can use the invention for further development or research related to this invention without the consent of the inventor. Even though patents provide substantial transparency, it can inhibit the flow of knowledge exchange. However, patents can provide the opportunity for reimbursement of research and developmental costs and ensures that an individual company/private organization does not make large profit from research funded by the government and public organisations. The index will assess the number of patents owned by the institute relevant to the focus areas of the Index, and evaluate whether it contributes and stimulates, or inhibits knowledge exchange.

Licensing (indicators: E.II.2)

A licence is a permit to do, use or own a patented invention that is not freely available. It may be granted under IP laws to authorise the use of a patented invention. Licensing allows other parties to participate in further research, development or selling a product. This makes information about the invention more widely available. The Index will assess how the institute organises their licensing practices, including selecting partners.

Partnerships (indicators: E.III.3)

While managing IP rights, an institute often collaborates with third parties. The Index will assess the selection of these partnerships.

BATI Methodology- explanation of the Indicators

A. General Management and Stakeholder Engagement

1. Governance

I.1 Governance: Management structures

The organisation has a management structure which covers the tasks and responsibilities concerning animal testing and the transition to animal-free innovation within the organisation.

2. Strategy

I.2 Strategy

The organisation has a strategic plan and sets both long- and short-term objectives to accelerate the transition to animal-free innovation and aligns its transition to animal-free innovation strategy with its core business.

3. Ethical Committees and Welfare Bodies

I.3 Ethical Committees and Welfare Bodies: Arrangement

The organisation commits to the optimal arrangement of the Ethical Evaluation Committee and the Animal Welfare Body to ensure optimal interaction and cooperation between all committees.

I.4 Ethical Committees and Welfare Bodies: Structure

The organisation sets index-related objectives for the ethical committees and welfare bodies to accelerate the transition to animal-free innovation within the organisation.

4. Managing for Index-related Outcomes

II.1 Managing for Index-related outcomes: Public reporting

The organisation publicly reports on its commitments, objectives, targets, and performance information related to the transition to animal-free innovation.

III.1 Managing for Index-related outcomes: Performance management system

The organisation has a performance management system to monitor and measure the outcomes and impact of its transition to animal-free innovation activities across the full scope of their operations.

III.2 Managing for Index-related outcomes: Incentives

The organisation has internal incentive structures to reward people and organisational units that effectively deliver transition to animal-free innovation initiatives.

5. Stakeholder Engagement

III.3 Stakeholder Engagement: Activities

The organisation engages with relevant stakeholders, including universities, industry peers, patient groups, local governments, employees, and local and international non-governmental organisations, with the aim of accelerating the transition to animal free innovation. The organisation has a system in place to incorporate local and other external perspectives on the transition to animal-free innovation in the development and implementation of its transition to animal-free innovation strategies.

B. Research and Development

1. Quality standards

I.1 Quality standards: Commitment to standards

The organisation commits to complying with standards of quality assurance and control and ethics when conducting animal experiments. These standards are at least consistent with the Dutch laws.

III.1 Quality standards: Compliance with standards

The organisation provides evidence of ensuring compliance with the standards it sets for quality assurance, quality control and ethics regarding animal research.

2. Development and Use of Animal Free Research Models

I.2 Development and Use of Animal Free Research Models: Innovative and adaptive R&D

The organisation commits to carrying out research focussed on the development of both innovative research models and adaptive formulations of its existing research models with the goal of accelerating the transition to animal-free innovation.

III.2 Development of Animal Free Research Models: Innovation

The amount of ongoing research reflecting the research on and development of innovative research models, including innovative and adaptive R&D, and in-house and collaborative R&D.

III.3 Use of Animal Free Research Models: Implementation

The amount of ongoing research using existing animal free research models in research that does not have the aim of developing new animal free innovations, compared to the size of the (animal) research facility of the organisation.

3. Collaborative R&D and Data Sharing

I.3 Collaborative R&D: Ensuring equitable access

The organisation commits to ensuring equitable access to animal-free research models successfully developed through R&D partnerships, in addition to equal access for the research departments to research facilities needed for the use and development of animal free research models.

II.1 Data sharing: Negative data

The organisation discloses information regarding the results of all its research conducted, regardless of the outcome, with the aim of reducing unnecessary duplication of animal experimentation and to avoid reporting bias.

C. Education and Training

1. Initial Education

I.1 Initial Education: Student curriculum

The organisation commits to the inclusion of subjects regarding animal experimentation, innovative (animal-free) research and the transition to animal-free innovation in the student curriculum of relevant educational programs, including biomedical and biopharmaceutical sciences and medicine.

III.1 Initial Education: Activities

The organisation undertakes educational activities for their students with the aim of informing students of the transition to animal-free innovation, animal experimentation and innovative (animal-free) research.

2. Continuing Professional Development

III.2 Continuing professional development: R&D capacity building activities

The organisation undertakes R&D capacity building activities for their researchers with the aim of accelerating the transition to animal-free innovation and maintaining the highest quality standards for the execution of animal experimentation.

3. Training Need Assessment

I.2 Training need assessment: Assessing training needs

The organisation commits to the assessment and provision of training needs aimed at reaching or maintaining the highest quality standards both for in-house and third-party researchers.

4. Awareness

I.3 Awareness: Internal knowledge exchange

The organisation commits to the arrangement of interaction and cooperation between different research departments with the aim of knowledge and skill exchange regarding innovative research models.

II.1 Awareness: Public reporting

The organisation publicly reports on its capacity building activities and awareness activities related to animal experimentation, innovative research, and the transition to animal-free innovation, including performance information and key outcomes.

III.3 Awareness: Activities

The organisation organises awareness activities with the aim of raising awareness on animal experimentation and the transition to animal-free innovation on the internal, external, and public level.

5. External Education

III.4 External Education: R&D capacity building activities

The organisation undertakes R&D capacity building activities in partnership with local universities and public and private sector research organisations that meet good practice standards with the aim of accelerating the transition to animal-free and maintaining the highest quality standards for the execution of animal experimentation.

D. Investments and Grants

1. Investments

II.1 Investments: Disclosure of resources dedicated to R&D

The organisation publicly discloses the resources dedicated to research on and development of innovative research models, including innovative and adaptive R&D, and in-house and collaborative R&D.

III.1 Investments: Resources dedicated to R&D

The financial R&D investment dedicated to research on and development of innovative research models, including innovative and adaptive R&D, and in-house and collaborative R&D.

2. Subsidies

III.2 Grants: Grants for R&D

The number and amount of acquired grants dedicated to animal-free research and research on and development of innovative research models, including innovative and adaptive R&D, acquired from Horizon 2020, ZonMW, NWO, Proefdiervrij and SGF.

E. Intellectual Property

1. Patents

II.1 Patent disclosure

The organisation publicly discloses the patent status of its patents related to the transition to animal-free innovation.

2. Licensing

II.2 Disclosure of licensing practice

The organisation publicly discloses detailed information about the voluntary licences and non-assert agreements it is engaged in for intellectual property related to the transition to animal-free innovation.

3. Partnerships

III.3 Partnerships: IP sharing

The organisation provides evidence of sharing its intellectual property with local universities and public and private research institutions that develop animal-free research models either through open access or through fair and reasonable licensing.