CHARTER OF COMMON VALUES OF THE ASSOCIATION

Preamble

Pursuant to article 2 of the Articles of Association, the Association pursues an aim of public interest contributing to improving public health, in particular to enhance the quality and relevance of the ecosystem of innovation in oncology for the benefit of all patients and in full compliance with the rules in force, in particular, those on the protection of people as regards the processing of personal data, notably with the following missions:

- Federate the public and private Founding Members as part of a national initiative that can benefit the entire ecosystem of innovation in oncology;

- Associate the data resulting from industrial projects with oncology-related data produced by public organisations, so as to extend the knowledge needed for patient care, using all suitable analysis methods and technology, and artificial intelligence in particular. To do so, the Association investigates and provides assistance for Cancer-related Data Reuse Projects (hereinafter "DRP") drawing on the expertise of its Members;

- Deploy and validate technologies that are likely to boost and facilitate DRPs, in particular those developed by start-ups and SMBs, and especially within the country;

- Encourage the industrial players to output oncology data in particular in keeping with quality standards and other applicable standards, to conduct the DRPs successfully, to promote interoperability and the provision of that data, especially the data used for the DRPs, on INCa's cancer data platform and the health data hub HDH;

- Develop and promote cancer research and encourage researchers and clinicians in their work on data in oncology.

The aim is to **improve the knowledge of cancers** so as to provide better patient care and more precise medicine and, in keeping with the spirit of the National Council of Industry (CNI) and the Sector Strategic Committee (CSF) from which this project stems, **stimulate the innovation ecosystem and create value**.

To carry out these missions, the Directors, Senior Managers, Collaborators, Founding Members, Partners, Qualified Persons and Stakeholders of the sector project clarify the spirit and principles below, in response to article 16 of the Articles of Association of the Association that prompts them to define the "principles, methods and procedures to adopt in terms of transparency and ethics when carrying out its missions".

The articles below set forth these principles. **They have guided this project since its inception and constitute the core that is essential to its working and future changes.** The articles below serve as an ethics charter and will be published on the Association's website.

This charter also includes **a series of fundamental measures to ensure compliance with competition law among the members of the association**. These items are detailed from Title 2, Article 6.

TITLE 1: COMMON PRINCIPLES OF THE PARTIES TO THE PROJECT

Article 1: Building trust around health data

The sector project participants consider that the trust of patients and, more broadly, of citizens regarding the use of health data is a fundamental challenge that they are committed to meeting.

As health data is becoming increasingly important, the participants consider that these developments are not ends in themselves but rather opportunities to develop a more precise and personalised medicine at the service of healthcare whose foundation remains the human relationship between caregivers and patients.

The Cancer Data Reuse Projects (DRP) must contribute to building this trust through the transparency of the means employed, objectives and expected results, aimed at improving the health path in oncology.

The sector project will ensure that the data processing to be carried out in each DRP complies with all applicable stipulations, and in particular the General Data Protection Regulation (GDPR), the Data protection act and the Public health code. These obligations relate both to legal aspects (proportionality principle, data minimisation, rights of individuals) and technical aspects (data security, authorisations).

In all these respects, the participants undertake to adopt a transparent and inclusive process for the emergence of DRPs. For each DRP proposed, before the file is submitted to the competent authorities (CESREES, CNIL), an opinion on the ethical relevance and public interest will be issued by the Scientific and Ethics Committee of INCa's cancer data platform. A report will also be issued subsequently by a Committee of the Stakeholders of the Association, composed of organisations that represent patients, users, healthcare professionals, organisations operating in the medical, medico-social or prevention areas, learned institutions or public research players.

Article 2: Conducting projects that address healthcare challenges

Progress in healthcare is justified when it improves the lives of patients and their family and friends, and when it helps practitioners in their mission.

In this respect, the participants undertake to conduct DRPs that will lead to innovative therapeutic and diagnostic solutions that address hitherto unanswered questions on the oncology health path, be it for the most common cancers or for rare cancers.

They also undertake to contribute outcomes that can be used to personalise the patient care or every patient, in this complex environment that undergoes rapid changes in terms of diagnostic tools, solutions and combination therapies.

The projects conducted by the participants account for criteria including the expected impact of the therapeutic solutions or tools on patient care, that are assessed according to current scientific standards.

To ensure transparency, the organisations that represent patients, users, healthcare professionals, the medical, medicosocial or prevention areas, learned institutions or public research players participate in the Association's committees to make recommendations will be made publicly available and published on the Association's website.

Article 3: Building an environment that is open to innovation

The objective of the National Council of Industry (CNI) and the Sector Strategic Committee (CSF) from which this project stems, is to stimulate the innovation ecosystem to create value on national territory. The Association steps up the access to interoperable, consistent and complementary oncology data for all, to address innovative issues and enable the creation of value for the patient by biotechs, and digital, diagnostic, therapeutic, and patient care industries.

This objectives are hinged on the INCa cancer data platform. INCa works with clinical practitioners to develop standardised clinical documents for the health path in cancer, and integrates them in the CI-SIS health information systems interoperability framework with Agence du Numérique en Santé. INCa contributes to integrating these repositories in the healthcare professionals' software on site and allows them to connect to the cancer data platform. With this interoperable data, the accessible analysis base is expanding on an unprecedented scale, with considerable scope for the attractiveness of the ecosystem, for public research and for healthcare.

The participants also undertake that any company, without distinction, can avail of the Association's assistance to carry out cancer data reuse projects. To encourage this openness and promote meetings, specific events are organized with the innovation ecosystem players. They are designed with the members and partners that are representative of the industrial fabric: companies specialising in networks, software and tools in the clinical context, in data analysis and artificial intelligence, in health technologies and diagnosis or in "real-world" patient care.

The objective is to design, test, improve, and leverage the innovations of these industries in concrete projects, in front of an audience that can attest to their efficiency and even support their international expansion.

Article 4: Conducting a sector project made up of decentralized projects

The sector project is made up of a series of cancer data reuse projects (DRP) carried out by the Association's industrial founders, partners or clients. These projects can be carried out on a national, regional or even local scale. They are spread across the territory.

For each DRP, feedback is organised within the Association that stands guarantee for the overall consistency and the ability to coordinate. The round table brings together the French National Cancer Institute (INCa), the Health Data Hub, the Health Industry Alliance for Research and Innovation (ARIIS), France Biotech and eight industrial founders from the pharmaceutical and diagnostic sector. In this regard, all feedback, best practices, model data access agreements, data documentation, and methods and procedures for matching data will

be documented and mapped, on the one hand to replicate, step up and amplify our successes, and on the other hand to limit the risk of failure by identifying the actions that will help find answers to the questions of tomorrow that remain unanswered today. These documents and maps will be made publicly available and published on the Association's website, and updated regularly by the Association.

Lastly, the participants undertake to remain open to initiatives to contribute to the growth of the Association.

Article 5: Maintaining and nurturing dialogue with civil society

The Covid-19 health crisis has shown that innovation in the health industry sparks many expectations in people, regarding scientific and therapeutic progress to bring about innovative, efficient, personalised and modern forms of treatment. However, the concept of progress in healthcare remains abstract unless the challenges are understood and access to effective care is made possible.

In this regard, the participants undertake to help explain the progress made in the field of cancer to the general public, by participating in initiatives and by communicating directly on the issues at stake using good teaching skills: what place does data hold in innovation? What is artificial intelligence in oncology? What promises does it hold, what is its development and limits? What is the importance of the dynamics of innovation in France? How important is it for its sovereignty tomorrow?

TITLE 2: COMPLIANCE WITH COMPETITION LAW

Article 6: Compliance with competition law within the Association

The Association and the Members are committed to maintaining healthy and fair competition to guarantee the proper functioning of the market and the development of innovation in conditions that are conducive to safeguarding the independence of companies in determining their individual strategies.

Being aware of their current or potential competitive relationships on certain markets, the Association's internal staff and Members undertake to abide by and apply competition law in its entirety, and in particular the principles and guidelines set forth in this charter, in order to prevent any behaviour that may have an anti-competitive purpose or effect in the context of their participation in the Association's activities.

Article 6.1: Key principles of competition law

In accordance with competition law, the Association and the Members undertake to determine their strategy and behaviour on the markets independently and to refrain from any agreement or concerted practice, in whatever form, whether express or implied, which may have a direct or indirect anti-competitive purpose or effect, such as:

- Restricting market access or the play of competition by other companies (whether or not they are Members of the Association);
- Obstructing the setting of prices by the free play of market forces by artificially favouring their rise or fall;
- Limiting or controlling production, market outlets, investment or technical progress, including research and development activities;
- Sharing markets or supply sources.

In particular, the Association and the Members shall ensure that they:

- Refrain from any exchange of sensitive information within the meaning given by competition law (including the unilateral disclosure of such information), except where strictly necessary and proportionate to the fulfilment of the legitimate objectives of the Project as recalled in the Preamble;
- Do to obstruct the implementation of the DRPs, whether proposed by Members or non-members;
- Ensure non-discriminatory and cost-oriented access by third parties to the Association's services and to the common databases established within the framework of the Association.

Article 6.2: Supervision of information exchange within the Association

Article 6.2.1: Excluded information exchange within the Association

The Members and employees of the Association undertake to refrain from disclosing any information of a strategic nature about their company and its activities or those of its members, in any form whatsoever, during the meetings and works of the Association or outside the Association, such as:

- Prices (including negotiations with authorities in charge of reimbursement and prices), price lists, sales policies or strategies, sales terms, discounts, profits, margins, market share, payment terms;

- Production or distribution costs, cost accounting formulas, cost allocation methods;

- Methods or sources of supply, production, inventory, sales, marketing or promotion;

- All business issues relating to suppliers or clients, positions taken with regard to certain client or supplier behaviours, positions or information relating to calls for tenders from clients subject to the Public Procurement Code, any reference or attempt at collective action aimed at excluding a supplier or customer from the market;

- Detailed information about the procedures of medical examinations (list of professionals seen, key opinion leaders contacted, etc.);

- Partnership projects, acquisitions, disposals or other strategic operations;

- Financial or strategic risks for a company, investments;

- All information on the organisation or individual development plans of a company relating to technology, research and development, development strategies according to the different therapeutic areas, including data from clinical trials that have been completed or are ongoing in phases 1 to 3, data from observational studies conducted during the development of health products or after they have been placed on the market, with the exception of the restricted list of situations given in article 6.2.3 below;

- All information on market entry strategies for products that are not yet marketed, including the content of applications for assessment, applications for temporary authorisation for use or temporary recommendation for use, applications for the authorisation to market, etc.

Article 6.2.3 Authorised exchange of information within the Association

Only information that strictly meets all or part of the following alternate terms and conditions may be transmitted within the Association:

- General and not strategic;

- Historical, i.e. at least one year old, excluding any current or future information;

- Public and non-confidential;

- Anonymised and aggregated in such a way that it does not allow identifying an individual member or practice. If the anonymisation or aggregation procedures are carried out by the Association or by an independent trusted third party, all appropriate measures must be taken to ensure that the confidentiality of the initial data processed is safeguarded.

However, in the specific case of DRPs that will be conducted within the framework of the Association, they may call for the use of data produced by public bodies *(in particular* data from the national health data system (SNDS), that has been requalified and validated, cancer registries and regional cancer screening coordination centres (CRCDC)), stored in the cancer data platform of the French National Cancer Institute - "**INCa** " - or made available by the Health Data Hub -**"HDH**" - in compliance with the applicable legislative and regulatory provisions, and private data collected or belonging to the Member or non-member third party that is the principal investigator of the DRP.

Should the DRPs call for the use of data produced by private organisations (a Member or a non-member third party), such data cannot be transmitted to the Association. For the purposes of processing that data within the framework of the relevant DRP and in order to guarantee the full confidentiality of that data, the private data bases relevant to said DRP shall be matched by external data sub processors, duly authorised, appointed for this purpose and managed by the Association.

Notwithstanding, a Member (as well as any non-member third party that is the principal investigator of a DRP within the framework of the Association) may, if it so wishes, transmit a private dataset to INCa so that it can qualify and document it, and integrate it into the cancer data platform, and, where appropriate, transmit the requalified dataset to HDH.

Article 6.2.4: Processing and returns by the Association

Any processing of data produced by private bodies that the Association may be required to manage in the context of its activity must guarantee a sufficient level of aggregation and anonymisation so as not to allow identifying a Member (or a non-member third party that is a principal investigator of a DRP within the framework of the Association) or of any information of a strategic nature relating to the latter's activity and projects.

In this regard, the Association only intends to pool, and undertakes to return to its Members or to make publicly available, only mappings, data typologies, and analytical methodologies resulting from the DRPs (such as methods of data selection, preparation, extraction, cleansing, matching, etc.) whose value for the Project's national data ecosystem operation has been demonstrated, and excluding the data (raw or reprocessed) itself provided and/or matched in connection with the DRPs.

TITLE 3: PRINCIPLES AND RULES OF FAIR PRACTICE

This title defines the fair practice framework in which the Association operates and sets the rules to be applied by persons who work with the Association in the performance of their duties.

In accordance with article 16 of the Articles of Association and article XX of the Association's Internal rules of procedure, this framework and these rules apply to all persons appointed by the Association to implement its missions, including:
- its CEO and its Managing Director;
- its internal staff;
- its Founding Members or future members;
- its Partner Members;
- its directors;
- members of the Stakeholders Committee

All of whom are hereinafter collectively referred to as "Employees".

Article 7: Rules of fair practice

7.1 Duty of probity and independence

Complete honesty is required in performing the missions. It is forbidden to receive money or benefits in exchange for influencing the work carried out within the Association.
All employees shall keep away from any situation that might call their independence into question.

7.2 Duty of impartiality

Under the duty of impartiality, issues must be handled with the utmost neutrality, backed by arguments and, where appropriate, based on rigorous methodology. The slightest breach of impartiality may vitiate the achievements of an employee, discredit all the work that he/she has participated in, or even discredit other work carried out by the Association.

7.3 Duty of professionalism

7.3.1 Personal performance of the mission

All employees are appointed in a personal capacity for their recognized skills. They may not delegate their mission to a third party, except by delegation of authority granted in keeping with the methods and procedures laid down in the Institute's internal rules of procedure.

7.3.2 Best-efforts obligation

All employees are required, with the means at their disposal, to make their best effort to devote themselves to their mission.
They must therefore carry out their mission scrupulously and, where appropriate, in compliance with scientific or technical methodology. It is important to fully document the details of how the mission was conducted, particularly with successively dated and numbered versions of the documents.

7.4 Duty of confidentiality

All employees are required to maintain professional discretion. In this regard, unless they obtain prior authorisation to do so, they must not disclose any facts, information or documents of which they become aware in the course of or in connection with the performance of their duties.

They must not disclose the work they produce, nor that is produced individually or collectively by the other employees of the Association, unless authorised to do so by the Association.

The employees may present the results of work that are made publicly available by the Association, subject to the duty of circumspection that continues to apply in any case after publication.

The duty of confidentiality shall not prevent the reporting of an alert under the conditions provided for by law.

7.5 Duty of circumspection

No employee may speak on behalf of the Association, including about its missions, unless duly authorised. On the other hand, they may become the Association's spokesperson on a subject that falls within the scope of their mission, if the Association so requests.
The duty of circumspection does not curb freedom of opinion, but it does impose restrictions on freedom of expression.
Employees must make a clear distinction between information validated by the Association and their own stance regarding that information, which is not binding on the Association. They must not use their collaboration with the Association to establish or strengthen their personal stance.
All employees shall ensure that their participation, in a personal capacity, in public debates concerning their mission is free from any critical assessment or personal stance that may cause harm to the public service to which they contribute.

Article 8: Prohibition on providing benefits

In accordance with the Association's internal regulations, it is not subject to the regulations governing the benefits provided by the health industries resulting from Article L. 1453-3 of the French Public Health Code. However, it prohibits its employees from providing benefits in cash or in kind, in any form whatsoever, directly or indirectly, to the persons mentioned in Article L1453-4 of the French Public Health Code.

Article 9: Conflict of interest

All collaborators are required to declare any financial or economic link or personal interest, direct or indirect, particularly through the organisation they represent, with the purpose of their mission (analysis, opinion, validation of a DRP, item on the agenda of a meeting, etc.) which would constitute a conflict of interest.

A conflict of interest is any situation in which said link could compromise the impartiality or independence of the employee in the performance of their mission or their assignment.

Any employee (including internal employees or administrators) cannot participate in the instruction or validation of DRP proposals / projects, if they have a direct or indirect link with the company carrying the DRP. He is required to report his links before the review of each proposal / draft DRP and, if there is no link, to sign a declaration of no conflict of interest. In the presence of a direct or indirect link, he does not take part in the work of instruction, or in deliberations, or in votes. These rules also apply to members of the Stakeholder Committee when they draw up an ex post facto report on the decisions of the board of directors on DRP proposals / projects. In addition, article 432-12 of the French Penal Code[1] relating to the

[1] Article 432-12 of the French Penal Code: The fact, by a person holding public authority or entrusted with a public service mission or by a person invested with a public elective mandate, of taking, receiving or keeping,

illegal taking of an interest applies to employees of the Association charged with a public service mission.

In addition, the persons involved in the examination (internal staff) or the validation of DRP proposals/projects (directors), but also those who subsequently report on the decisions of the Board of Directors on these matters, undertake not to be able to benefit financially, professionally or personally from the validation of the DRP proposal/project that they examine, validate or on the decision of which they have to report, whether for themselves, their family and friends or the organisation they represent.

In this case, they must report it and not take part in the discussions, votes, opinions and recommendations.
As regards directors specifically, in application of article 12.4.4 of the Articles of Association, they cannot participate in the works or deliberations or votes of the Board of Directors if they have a stake, direct or indirect, in the matter under discussion.

Article 10: Entry into force

This charter shall come into force once it is approved by the Association's Board of Directors. It is distributed internally and published on its website.

directly or indirectly, any interest whatsoever in a company or in an operation for which it has, at the time of the act, in whole or in part, the supervision, administration, liquidation or payment, is punished by five years' imprisonment and a fine of € 500,000, this amount may be doubled according to the object of the offense.