

## Governance Charter for the GoCART Coalition

### 1. Background

Despite progress in saving lives of patients with haematological diseases – whether neoplastic or benign – as well as solid tumours, many patients eventually develop resistance or relapse, and mortality rates for this population are still unacceptably high. Cellular therapies manufactured from cells of hematopoietic origin provide a promising treatment option for these patients, yet there are considerable challenges in the implementation of therapies in this rapidly evolving field. These include but are not limited to the complexity of the therapies and their production, requiring centre qualification as well as additional and ongoing education of health care professionals, the long term follow up of patients treated with therapies with a curative intent, the myriad of regulatory requirements at European Union and local level for the conduct of post authorization studies and reimbursement of the treatments by budget-constrained authorities. One important step forward would be the establishment of a European multi-stakeholder coalition with all stakeholders to effectively work together to maximise the potential of cellular therapies.

### 2. Purpose of Charter

This document constitutes the Governance Charter (Charter) of the GoCART Coalition, a multi-stakeholder coalition of patient representatives, pharmaceutical companies, health authorities health care professionals in the field of cellular therapies prepared from cells and tissues of hematopoietic origin, and used to treat haematological diseases. Its purpose is to detail how the Coalition is organised, outline participation eligibility, define its leadership structure, and stipulate the rules and regulations pertaining to the election of its Executive Committee and work ethics of the Executive Committee. This Charter exists to ensure clarity, integrity, accountability, relevance, effectiveness, sustainability, and impact of the Coalition. This document will be reviewed as necessary to ensure that it continues to support the GoCART Coalition's mission and activities.

### 3. Name of the Coalition

The official name of this multi-stakeholder coalition is “the GoCART Coalition”.

### 4. Mission, vision and values of the Coalition

#### 4.1. Mission

Our mission is to be leading force in the field of cellular therapies and trusted partner to promote patient access to novel cellular therapies and to contribute health and well-being through multi-stakeholder collaboration on clinical data, standards of care, education and policy.

#### 4.2. Vision

Our vision is to create a platform driven by input of a diverse group of stakeholders who jointly develop projects that advance the field of cellular therapies in Europa.

#### 4.3. Values

Our core values underlying the activities of the GoCART Coalition are:

- Patients-centred – the GoCART Coalition exists to save and improve patients' lives. We take decisions and measure outcomes based on how well it serves patients;
- Build relationships and deliver results – we believe in the power of working together to rise to the challenges in the field of cellular therapy;
- Creating value by sharing data and knowledge – by adopting the principle 'collect once, use often' data and knowledge sharing will support better decision making and drive efficiencies for all stakeholders;
- Transparency breeds trust – we believe in open, honest and respectful communication and decision making;
- Grow and adapt – we cannot predict the future, but we are ready for the challenges that come our way and are committed to ensure lasting impact and sustainability of this Coalition.

## 5. Goals of the Coalition

The aims of the GoCART Coalition are to:

- Improve health outcomes for patients;
- Engage stakeholders and establish a sustainable European coalition in the field of cellular therapy;
- Collaborate and share data and knowledge to prevent duplication of effort and resources;
- Promote harmonisation of data collection, education, standards of care and policies in Europe;
- Support the set-up and maintenance of a pre-and post-authorisation registry that informs decision making and support shared research purposes;
- Develop a cellular therapy Education and Information program for patients and health care professionals;
- Harmonise standards of care and centre qualification;
- Advance policies that further the shared mission and vision.

## 6. Legal structure

The GoCART Coalition is a partnership of legal entities. At present, it does not have a legal form or personality of its own; however, the Coalition may decide to become a legal entity in the future.

## 7. Participation

### 7.1. Participants

The GoCART Coalition is open to all stakeholders relevant to achieve its mission. The GoCART Coalition has two categories of participation: institutional participants and individual participants. An institutional participant is considered to be a legal entity such as an association or company and has the right to appoint or be appointed as Executive Committee participant(s). Individuals who support the Coalition's mission and vision and want to participate in the Coalition's activities can become an individual participant. All participants contribute their time to the GoCART Coalition pro bono.

The Coalition's institutional participants consist of all those duly registered with the Coalition and are grouped in the following categories:

#### 7.1.1. Founding organisations

The GoCART coalition is founded by the European Society for Blood and Marrow Transplantation (EBMT), with the European Hematology Association (EHA) as co-founder.

#### 7.1.2. Patient advocates

Patient advocates are individuals or organisations operating at EU level representing patients with diseases for which the utility of treatment with cellular or gene therapy manufactured from hematopoietic tissues or cells is proven or explored.

#### 7.1.3. Medical organisations

Medical organisations are transplantation/cellular therapy groups and disease oriented health care professionals organised in scientific societies / cooperative groups operating at national or EU level supporting the Coalition's mission.

#### 7.1.4. Industry partners

Industry partners are companies involved in the development or manufacturing of gene and cellular therapies from cells and tissues of hematopoietic origin. The platform is open to companies working on cellular or gene therapies for haematological diseases as well as cellular or gene therapies for non-haematological cancers, however in the start-up phase the focus of the Coalition will be on cellular or gene therapies for haematological diseases as proof of efficacy was originally brought for this category of diseases.

#### 7.1.5. Health authorities

Health authorities are defined as competent authorities responsible for human medicines and substances of human origin operating at national and EU level. Also included in the group of health authorities are Health Technology Assessment (HTA) bodies, payers, pricing and reimbursement agencies from different EU countries.

### **7.2. Partnership rights**

Institutional participants have the right to:

- Appoint Executive Committee participants;
- Be appointed to any vacant position on the GoCART Coalition's Executive Committee or another office within the Coalition;
- Participate in work packages activities;
- Receive information about the Executive Committee and other activities, co-operative studies and policies and results of the Coalition's projects.

Individual participants have the right to:

- Participate in work packages activities based on the participant's expertise;
- Receive information about the Executive Committee and other activities, co-operative studies and policies and results of the Coalition's projects.

### **7.3. Responsibilities of the participation**

Each participant will agree to the following:

- participants are expected to actively participate in the GoCART Coalition's meetings or activities;
- Support the GoCART Coalition's mission and goals in undertaking any activities related to the Coalition;
- Contribute to shared learning, accountability, and collective action among the GoCART Coalition participants.

#### **7.4. New participation**

Participation is open to any stakeholder with a relevant mission as the coalition, whereby candidates for participant commit to active participation in and adherence to the values of the GoCART Coalition.

A prospective institutional or individual participant shall submit a statement of interest to the GoCART Coalition secretariat. Based on this submission and following appropriate due diligence, the secretariat shall make a recommendation to the Executive Committee regarding the prospective participant's suitability to participate in the Coalition.

The decision on institutional participation shall be taken by the Executive Committee. If consensus cannot be achieved the prospective participant shall be declined.

#### **7.5. Termination of participation**

- A participant may choose to resign participation of the GoCART Coalition at any point by filing notice to the Executive Committee and secretariat. Any institutional participant who withdraws from the group may again apply to become a participant, subject to the approval of the Executive Committee as described above.
- The Executive Committee of the GoCART Coalition shall also have the right to terminate the participation of any party who, after appropriate notice and opportunity to remedy:
  - Fails to live by the GoCART Coalition's participation requirements or other commitments;
  - Discloses of information identified as confidential.

#### **7.6. Meetings**

The participation will convene at least once a year at a time and place designated by the Executive Committee.

Meetings notice: Notice shall be sent at least four (4) weeks prior to the date set for the meeting. Notice may be sent by any written means of communication, including but not limited to electronic mail, and postal mail, and shall be considered sent on the day it is transmitted by the sender.

Individual Work Packages and Work Groups will meet at a frequency deemed appropriate for the conduct of the activities.

### **8. Executive Committee**

#### **8.1. General responsibilities**

The Executive Committee is the primary decision-making body of the Coalition. With input of the Coalition participants and Work Packages, it steers the major strategic decisions and function of the Coalition including the amendment of the Governance Charter, the directions of all work packages, definition of the annual programme, budget allocations, approval of new participants, all written materials with positions outside the agreed communications mandate. The Executive Committee approves changes in the governance structure.

#### **8.2. Structure**

The Executive Committee shall consist of eight (8) representatives with a designated number of seats defined per stakeholder category. The Executive Committee shall consist of interested persons distinguished by their achievement and good judgment who have expertise in areas which will aid the GoCART Coalition in the development and implementation of the mission and vision, and who shall

broadly represent the cellular and gene therapy community in Europe and the representatives of the Coalition. The Executive Committee shall include:

- Founding organisations 2 representatives (EBMT and EHA, each one seat)
- Medical organisations 2 representatives
- Patient advocates 2 representatives
- Pharmaceutical companies 2 representatives

In addition to the foregoing, the GoCART Coalition will allow two (2) representatives of Health Authorities to attend all Executive Committee meetings in a non-voting observer capacity.

The above described structure and decision making and consensus development systems (see section 8.5. below) will be reviewed regularly to ensure that the structures continue to support a fair balance of representation between participants and the sectors they represent.

An Executive Committee representative who is unable to attend a meeting, should ensure that their stakeholder category is represented with an alternate participant/deputy, who is fully briefed and has decision-making authority on behalf of the absentee representative.

### **8.3. Chair**

The chair of the Executive Committee of the GoCART Coalition will serve for two (2) years and will rotate among the founding organisations. The chair manages the activities of the executive committee.

### **8.4. Vice Chair**

The vice chair of the Coalition will serve for one (1) year and will rotate among the non-founding representatives of the Committee. The vice-chair will serve as the chair during the chair's absence.

### **8.5. Executive Committee representatives**

Each stakeholder group will develop its own process to designate its representatives to the Executive Committee and determine the participants of its delegation.

### **8.6. Term of office**

The term of office of the Executive Committee representative is one (1) years, with limitation of two (2) terms. No representative can serve more than two (2) terms including two (2) consecutive terms or two (2) non-consecutive terms.

### **8.7. Decision making**

The Coalition is led by consensus and a consultative based model, whereby:

- Each Executive Committee representative shall be entitled to one (1) vote on each proposition submitted to vote, with all votes having equal weight.
- Any decision that impacts a participant's internal processes, allocation of resources and/or legal obligations can only be implemented with the explicit approval of the individual participant(s) concerned.

The Executive Committee Chair and Vice Chair shall use best efforts to facilitate decisions by consensus. Where diverging views exist between representatives of the Executive Committee, the following mechanism will be put in place;

- Where representatives have failed to express an opinion/vote, they will be considered as an abstaining party to the discussion;
- Two representatives with opposing views will be asked to discuss directly and produce a compromise position to be presented to the representatives;
- If all practical efforts by the representatives, Chair and Vice Chair have not led to consensus and no compromise can be found, representatives will vote on the competing views:
  - Where the issue at hand concerns a change to the Coalition structure, participation, decision-making, mode of operation, finances Work Package chair nomination, or disciplinary measures, a two thirds majority shall be required to decide the vote;
  - Where the issue at hand concerns matters other than those described above, a simple majority shall be required to decide the vote. In case of a tie vote, the two representatives that represent the Coalition's founding organisations shall have the deciding vote. If they disagree, they try to reach consensus or come with a new proposal.
- If the vote cannot be taken during the meeting, it may be done by electronic mail – representatives can choose to make their vote known to the representatives (reply to all) or solely disclosed to the secretariat.

Non-voting observers have the following rights:

- Comment on proposals for policy development or decisions to be taken by the Executive Committee, and offer non-binding advice.

If the participation of the GoCART Coalition changes significantly, the above-described voting and consensus development systems will be reviewed to ensure that the systems continue to support a fair balance of representation and influence between participants and the sectors they represent.

## **8.8. Meetings**

There shall be at least four (4) quarterly regular meetings of the Executive Committee annually. The chair may call special meetings of the Executive Committee and shall call special meetings upon the written request of three (3) Executive Committee representatives.

Meetings notice: Notice shall be sent at least four (4) weeks prior to the date set for the meeting. Notice may be sent by electronic mail.

Minutes: Upon approval by Executive Committee participants, minutes of the Executive Committee meetings shall be circulated among Work Package chairs.

Quorum: The Executive Committee may have meetings only when at least one of the representatives of each of the stakeholder categories and both cofounding participants are present.

## **9. Work packages and work groups**

### **9.1. Roles and responsibilities**

The GoCART Coalition organises its activities through its work packages. The work packages cover an area of interest of the Coalition and ensure the implementation of the strategy on which the Executive Committee has agreed. Within work packages smaller work groups may be established to conduct specific projects. See Annex 1 for a description of the work packages and their aims. This document will be maintained independently of this Charter.

## **9.2. Structure**

Work packages are defined by the Executive Committee and consist of a group of participants active in pursuing the aims of the work package. Each work package is headed by a chair, who is appointed by the Executive Committee. Participants can be invited to become participants in a work package and/or work group by the work package chair or secretariat. Alternatively, they can express their interest to participate to the chair of the work package or secretariat.

## **9.3. Decision-making rules**

In the work packages and work groups:

- Participants shall always strive to reach consensus;
- Any decision that impacts participant's internal processes, allocation of resources and/or legal obligations can only be implemented with the explicit approval of the individual participant(s) concerned;
- In the event consensus cannot be reached on a critical issue, the issue will be brought to the Executive Committee.

## **10. Secretariat**

There will be a secretariat that handles all aspects of the day-to-day organisation and administration (including financial and accounting functions) as well as the external engagement and communications efforts.

The secretariat's role is to:

- Run day-to-day activities of the GoCART Coalition;
- Support the drafting of official documents, position papers and advocacy materials;
- Support the implementation of the strategy on which the participation has agreed;
- Make sure all participants have the information and talking points they need to speak on behalf of the Coalition.

## **11. Intellectual Property**

For Work package and/or work group activities and projects that are expected to generate Intellectual Property, a separate agreement will be drawn up between the participants that are participating in this project.

## **12. Compliance with codes of conduct and antitrust/competition laws**

The GoCART Coalition will be operated in accordance with applicable European-level and national codes of conduct. Antitrust/competition laws apply to the establishment and operation of this Agreement and all signatories agree that they and all employees of their company will adhere to the above non-comprehensive guidance and to all applicable antitrust/competition laws.

The Parties shall respect all applicable antitrust/competition laws, and in particular shall refrain from engaging in (formal and informal) alignment, discussions or sharing of competitively sensitive information in relation to commercial or development strategies (including commercial or development responses to particular policy areas), price/price components, costs, sales, production/output, customers, market shares, terms agreed with purchasers or suppliers or other partners, confidential R&D programmes, and how and in what areas Parties conduct R&D.