

European Technology Platform on Nanomedicine

Terms of Reference (ToR)

Version - 28th January 2008

Mission

The **objectives** of this European Technology Platform (ETP) are to write a **Strategic Research Agenda (SRA)** in the area of Nanomedicine and to encourage its implementation through FP7, national and regional programmes as well as industry and academia. The ETP's objective is to strengthen **the long-term** scientific and industrial position of Europe in this applied field. It is important that this initiative provides patients with new, effective and affordable medicines, medical devices, therapies and diagnostics.

The **vision document** that was used as basis for the SRA and the final 2007 SRA is published and is available at: <http://cordis.europa.eu/nanotechnology/nanomedicine.htm>

To achieve the objectives, the activities of the ETP Nanomedicine will include the following **activities**:

- Setting up an efficient structure including an Executive Board, Working Groups, a Mirror Group and an Office to establish and implement the SRA and to update it annually.
- Provide high-level advice for future Community strategies and funding schemes in the area of Nanomedicine;
- Promote alignment between funding programs of the EU and national activities.
- Make recommendations on roadmaps, operational mechanisms and supporting studies for implementing the SRA.
- Evaluate the overall results and benefits of the SRA and the ETP for EU Member s and Associated States, the Commission and other Stakeholders.
- Recommend measures for addressing horizontal issues like toxicology, IPR, safety, ethics, regulation, standardisation, training, public perception, environmental aspects, need for infrastructures, measurements and testing, etc.
- Co-operation with relevant initiatives outside and inside the EU.
- Steer the development of any new legal structures that might be needed to ensure the effectiveness of the ETP as a public -private partnership.
- Facilitate communication and understanding between healthcare providers and academic groups working in this area, with the aim of improving patient care.

The ETP has identified the three Applied Science areas shown below and several horizontal issues:

- **Nanotechnology-based diagnostics, including imaging**
- **Targeted drug delivery and release**
- **Regenerative medicine**

- **Horizontal issues** linked to these three topics include accessibility to patients and the market, (eco -)toxicology, IPR, safety, ethics, regulation, training, public

perception, need for infrastructures, measurements and testing, metrology, standardisation, etc.

1. ETP Membership

Members of the ETP will be companies, hospitals, research organisations, and concerned organisations that **operate in the area of Nanomedicine**, represented by individuals (member representatives) that are able to contribute significantly and can give high-level advice to the European Commission and other stakeholders in the strategic planning and initiation of research programmes. As a rule, member organisations must have substantial R&D activities in the area of Nanomedicine in one or more of the EU Member States or Candidate States, or States associated with running Framework Programmes. Other concerned organisations, e.g. patient organisations, can also join. Initial members of the ETP are the parties that drafted and/or endorsed the vision document. Additional members can join the ETP upon invitation or submission of an Expression of Interest (EoI), subject to approval by the Platform. For the sake of openness and transparency, an open call for expressions of interest for joining the ETP, is posted on the internet. The EoI submissions will be reviewed by the Executive Board and the voting members of the ETP. Applicants should ensure they have the official approval of their organisation and that there are no multiple applications from the same organisation. The name of the person authorised to represent the member organisation and the type of the organisation (in terms of the fees category in Annex 1) should be clearly indicated in writing at the time of joining or renewal of membership. A representative's voting rights can be transferred to another member of the organisation, but this must be notified to the ETP contact person in writing. Staff of member organisations are welcome to attend ETP meetings as observers, within reasonable numbers and subject to prior written notification to the ETP contact person.

The functions exercised by the members of the ETP bodies will not be subject to specific remuneration or reimbursement.

Any organisation willing to become a member of the ETP has to fulfil the following requirements:

1. The applicant is from a Member, Associated or Candidate State of the European Union (exceptions are made on a case by case decision for third country applicants with important research activities in Europe).
2. The member organisation carries out substantial NanoMedicine R&D activities in Europe (exceptions are made e.g. for patient organisations).
3. The member representative is committed to investing the required time and energy into the Platform.
4. The member representative is able to give high-level advice to the Platform.

5. The member organisation or representative is prepared to pay membership fees of the Platform and to accept the Terms of Reference.
6. The member representative agrees to contribute to the Platform without remuneration and to pay his/her own travel and subsistence costs.

The ETP membership is the main decision making body for the Strategic Research Agenda. The activities of members include:

- Facilitation of an environment to bring Nanomedicines to patients
- Driving the definition and updating of the SRA, overseeing its implementation
- Yearly Conference on Nanomedicine
- Approval of new members, election of the ETP chairs after the start-up period
- Proposal and approval of new Working Groups, election of the WG chairs
- Approval of changes in the organisation or in the Terms of Reference for the ETP

Membership of the Platform/Voting Rights

Industry and hospitals will have the major share of voting rights (ie greater than 50%). If necessary this will be ensured by normalisation – by reducing the contribution of the potentially more numerous academic members votes to 50% less one vote. Participation in the different working groups is possible without being a member, upon invitation of the WG Chair.

Platform members agree to invest sufficient time to play an active role in its work and, in particular, to attend all plenary meetings of the Platform. The personal commitment of member representatives is essential and their substitution in meetings is strongly discouraged.

Operational Issues

The Platform is a self-regulated body, operating in a transparent way. Issues raised by at least ten percent of the members of the Platform will be discussed. The Platform, acting *via* the Executive Board, decides when, where and what it will discuss. Platform meetings will be held on a regular basis, typically two times a year. If the Platform needs to make a formal decision, the decision is proposed by the Chair(s) and adopted if there is consensus; if no consensus is reached, voting will be on a majority decision; if more than one third of all members have a different position, this will be reported. With the consent of the Chair(s) of the Executive Board, the Platform may invite *ad-hoc* observers to participate in its meetings for those topics for which this is felt to be beneficial. All materials are to be kept confidential until released by the Platform.

Changes in Membership

Any organisation that fulfils the requirements and is interested in becoming a member of the Platform may send an application to the ETP contact person.

This application should include the following:

- An expression of interest
- A description about how the organisation will contribute to the ETP's activities
- A description of their R&D activities in the field of nanomedicine (as defined in the vision paper). This could be a list of publications in peer -reviewed journals, or a description of development projects
- The CV of the representing contact person
- The web site address of the applying organisation

This application is reviewed by the Executive Board, which decides by simple majority, whether the outlined R&D activity and contribution is sufficient or not.

The ETP contact person will then collect the retained applications and get approval of the voting members of the ETP, either in a meeting or *via* e-mail. Every rejection needs to be duly justified by the rejecting members. The Executive Board will examine every single case of rejection and take the final decision on the submitted application.

Any new member organisation is asked to sign a letter of intent committing his/her institution to the ETP.

Organisations are free to change their representatives at the Platform by informing the ETP contact person in writing of the termination of authorisation of their former representative and the appointment of the new one. The successors would have to be individuals of high standing, in line with the aforementioned selection criteria for members of the Platform. If possible, the departing member should introduce the incoming members in his/her last meeting. In the event that a vote takes place, the departing member still present at the meeting would have the right to vote and the new member would have an observer status in that meeting.

If a member organisation of the Platform continuously demonstrates a lack of commitment, or fails to fulfil its duties towards the ETP, e.g. does not contribute to the SRA, it could be excluded from the ETP by a simple majority decision of the Executive Board.

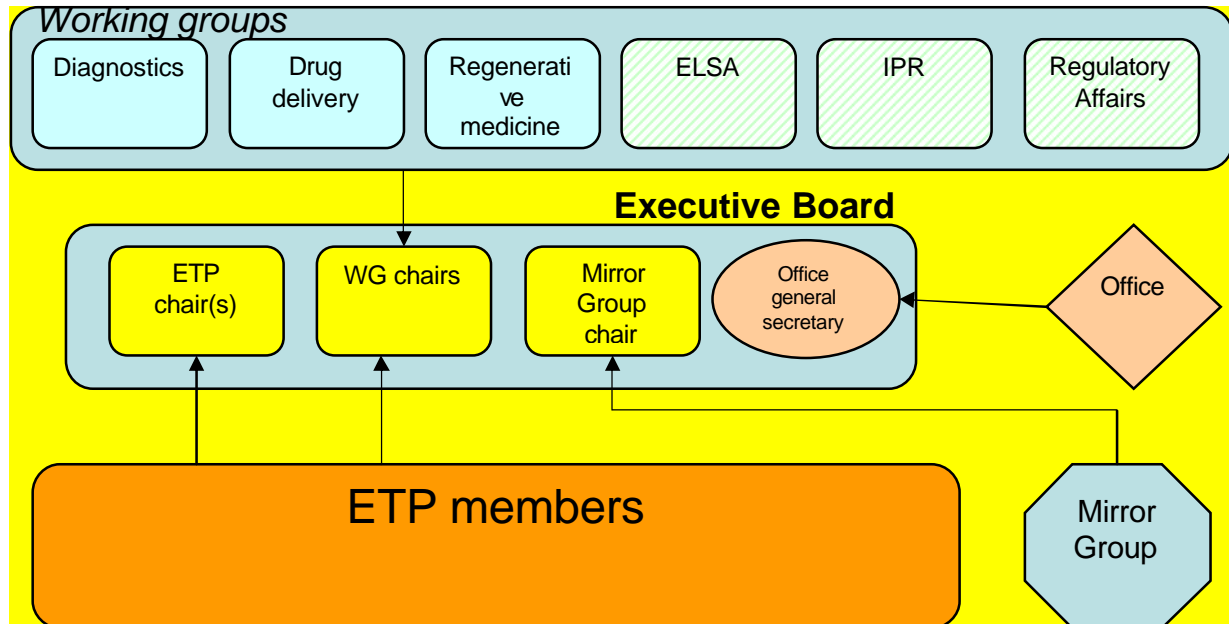
Representation and Quorum

The personal commitment of member representatives is paramount and their substitution in meetings is strongly discouraged. Substitutes will be allowed to participate in meetings as voters and to contribute to the discussions, on behalf of the member but notification in writing to the ETP contact person is required. Member organisations may also send (a limited number of) observers to meetings of the ETP but the ETP contact person should be notified in writing.

Meetings of the Executive Board shall not take place if a majority of its members are unable to attend.

2. Structure

Structure at 2007



3. Executive Board

The Executive Board, a smaller executive and operational representation of the Platform, will be set up in the interest of dynamic and efficient management and internal communication.

Responsibilities of the Executive Board

- Internal coordination and overall day -to-day management
- Preparation of Platform meetings and decisions
- Chairperson (or delegate) presides over Platform
- Starts Working Groups and monitors their results
- Approves new members of the Working Groups on a proposal from the chairperson (s) of the Working Groups
- Proposes and monitors implementation activities
- Promotes the Platform to the European Commission and other Public Authorities
- Interfaces with other stakeholders and related Technology Platforms
- Meets at least twice a year

- Decision preferably by consensus (if not possible by majority voting)
- The Executive Board establishes and manages international co -operations with comparable initiatives.
- For specific tasks like managing international relations the Executive Board may install an Advisory Group .

Composition of the Executive Board

The Executive Board consists of the chairperson(s) of the ETP or their delegates, the chairpersons of the Working Groups (with voting rights); the office General Secretary, once an ETP office will be operational; and representatives of the European Commission with observer status (without voting rights).

- For the initial period until the start of FP7, the chairpersons were Jouko Karvinen (Philips Medical Systems) and Erich Reinhardt (Siemens Medical Solution), on invitation of the European Commission.
- After the initial period, a chairperson(s) is elected by the Platform. The chairperson (s) need(s) to come from industry.
- The period of office for all chairpersons is two years (renewable).
- Should a chair be unable to continue for whatever reason the Executive Board can appoint a caretaker chair until such time as an election can be held.

Representatives from relevant European programmes or platform acting in the field of nanomedicine could be invited to attend the ExB o meetings as observers.

4. Working Groups

Working Groups are proposed for specific tasks by the Executive Board. Such tasks can be topical priorities of the Strategic Research Agenda, horizontal issues or other predefined tasks, such as recommendations for infrastructure and international cooperation.

The mandate of such Working Groups and any new ones shall be decided by the Platform on a proposal from the Executive Board, as well as their chairpersonship, structure and reporting mechanisms.

The chairperson(s) of the Working Groups are elected by the Platform and will come from industry for the technical working groups: targeted drug delivery, regenerative medicine, diagnostics and IPR. However, if the Executive Board recognises that a non - industrial candidate is especially qualified for the chairpersonship, it may allow a candidature by a simple majority. The WG chairperson from industry may decide on installing a non-industrial vice-chairperson, or vice versa, in the exceptional case of a non-industrial WG chairperson, he/she may decide on installing a vice -chairperson from industry.

If the Executive Board sees a need to establish a new Working Group between the meetings of the Platform, it may appoint an interim Working Group Chairperson, until an election can be carried out at the next meeting of the Platform.

If required, Working Groups may set up sub -Working Groups. The decision to establish a sub-WG will be made by the chairperson of the WG.

The chairperson of each Working Group will propose mem bers for the WG to the Executive Board, which can approve their membership by simple majority. The chairperson of the Working Group will report the activities of the WG to the Executive Board and to the Platform at their respective meetings.

Decisions in the Working Group are reached by consensus, if this is not possible, then by majority voting. Should serious differences of opinion arise in a Working Group; the chairperson can refer the issue to the Executive Board for resolution. If required, the Chairperson can invite concerned experts (non ETP members) to join WG activities and meetings.

The Initial Set of Working Groups (WGs) is:

Science Working Groups:

- **WG on targeted drug delivery**
- **WG on regenerative medicine**
- **WG on diagnostics**

These WGs will work out the content of the Strategic Research Agenda for their specific field. Their work will be coordinated and monitored by the Executive Board. They will involve representatives from academia, industry and concerned organisations for the respective fie ld and interface with professional associations in their respective fields.

Horizontal Issues related Working Groups:

- **WG on ELSA Issues**

This WG will interface with the governmental and public bodies, representing the initiative to the broader public and to increase the public acceptance of Nanomedicine.

- **Regulatory issues**

This WG will help shape the regulatory environment for nanomedicines, especially in new areas such as regenerative medicine. It will act as a forum for discussion and as an advisory group to the commission.

- **WG on Intellectual Property Rights**

This WG will work out rules for the treatment of intellectual property rights in research projects that develop out of the ETP.

5. Mirror group

The Mirror Group ensures the participation of Public Authorities at national, regional and European level in their function as policy makers, regulators and funding bodies. The aim of the Mirror Group is to develop synergies between national programmes and policies, pool resources to support the implementation of the SRA and to promote a fertile innovation environment and a state-of-the-art research infrastructure in Europe. A key role will be to facilitate the industrial academic interface from a European level down to regional levels. The mirror group chair will be a member of the executive board.

6. Office

An Office will be created and should take care of the tasks listed below.

Responsibilities of the Office

- Organisational, secretarial and operations support to Platform, Executive Board, WGs, Sub-WG's, Annual Conference, etc.
- Information and Communication centre for Nanomedicine ETP, incl. Website
- IT support
- Financial matters of Nanomedicine ETP operations
- Coordination, follow-up and consistency of WG activities
- The office general secretary will participate in the meetings of the Executive Board with observer status (without voting rights)

At this point (January 2008) , the funding of the office has not been secured. Therefore, until such funding is established, the responsibilities of the Office will be organised as follows:

- The secretariat of the Executive Board will be ensured by the ETP Chair(s).
- The secretariat of the Working Groups will be ensured by each WG Chair(s).
- The secretariat of the Platform will be ensured by the Commission.
- The secretariat of the Mirror Group will be ensured by its chairman's office (from the TOR of MG).
- The Commission will maintain the dedicated web -page and open an electronic tool (SINAPSE) to allow exchange of documents, filing etc.
- All secretariats will send to the Commission copies of their reports, agenda, and minutes of the meetings, etc. for archiving.

7. General Issues

Costs and funding

- All participants cover their own costs.
- A Budget framework was established at the 2007 General Assembly in Chalkidiki. The ETP budget will be managed by the Office and will be run from membership fees. The membership fees are determined by majority vote of the Executive Board and are subject to approval (as per section 'Operational Issues') of the Membership. The membership fees per annum are presented in Annex 1 to the ToR.
- For potential additional tasks, funds will be sought through e.g. SSA or CA projects.
- Individual R&D projects seek funding through regular public programmes at Community, intergovernmental, national and regional levels.

8. Update of the Terms of Reference

The Terms of Reference can be updated by the Platform at any time on request of at least ten percent of the members of the Platform or on request of the Executive Board. To be approved, a change request for the ToR requires both the majority of votes of the Platform members and the majority of votes of the Platform members from industry. Only if both conditions are met, will the change will be incorporated in the ToR.

Annex 1: Membership fees per annum

Industry > 5,000 employees	20.000€
Industry > 250 employees	10.000€
SMEs 16 – 250 employees	1.500 €
SMEs <15 employees	1.000 €
Healthcare providers	1.000 €
Academia, research centres and associations	500 €