

# **European Technology Platform on Nanomedicine**

## **ETPN**

### **Terms of Reference (ToR)**

*Update - 1<sup>st</sup> July 2013*

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## 1. Mission

The **objectives** of the European Technology Platform on Nanomedicine (ETPN) are to define Strategic Research and Innovation Priorities in the area of Nanomedicine in Europe, to elaborate and update the **Strategic Research and Innovation Agenda (SRIA)** and to encourage its implementation through European Framework Programmes, national and regional programmes as well as through industry and academia. The ETPN'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 first **vision document** as well as all strategic documents produced by the Platform are published and are available at: <http://www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications>

To achieve the objectives, the tasks of the ETP Nanomedicine include but are not limited to the following **activities**:

- Manage an efficient structure including an Executive Board, Working Groups, Task Forces, a Mirror Group and a Secretariat to establish, implement, and regularly update the SRIA;
- Provide high-level advice for current and future Community strategies and for funding schemes in the area of Nanomedicine in Europe;
- Promote alignment between funding programs of the EU and national activities;
- Make recommendations on roadmaps, operational mechanisms and supporting studies for implementing the SRIA;
- Evaluate the overall results and benefits of the SRIA and the ETPN for EU Members and Associated States, the Commission and other Stakeholders;
- Recommend measures for addressing horizontal issues like toxicology, IPR, safety, ethics, regulation, standardisation, education & training, public perception, environmental aspects, need for infrastructures, measurements and testing, etc.;
- Co-operation with relevant initiatives inside and outside the EU;
- Steer the development of any new legal structures that might be needed to ensure the effectiveness of the ETPN 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;
- Strengthen the Healthcare supply chain in Europe from Academics and especially SMEs through to global marketing companies.

The research priorities of the ETP Nanomedicine represent the core fields of interest of the members of the technology platform and are:

- **Nanotechnology-based diagnostics, including imaging**
- **Nanotherapeutics: Nanopharmaceuticals and Drug Targeting**
- **Regenerative Medicine and Biomaterials**

**Horizontal issues identified by the ETPN and** linked to these three topics include business opportunities, access to clinics, accessibility to patients and the market, environmental impact, IPR, safety, ethics, toxicology, characterisation, regulation, education & training, public perception, need for infrastructures, measurements and testing, metrology, standardisation, etc..

## 2. ETPN Membership

Members of the ETPN can be companies, universities, hospitals, research organisations, associations, 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. Members can join the ETPN 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 ETPN, is posted on the internet. The Eoi submissions will be reviewed by the Executive Board. 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 ETPN Secretariat in writing. Staffs of member organisations are welcome to attend ETPN meetings as observers, within reasonable numbers and subject to prior written notification to the ETPN Secretariat.

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

### Application for membership

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

1. The applicant organisation is a legal entity from a Member, Associated or Candidate State of the European Union (exceptions are made on a case by case decision for third country applicants);
2. The member organisation carries out substantial Nanomedicine R&D activities in Europe (exceptions are made e.g. for patient organisations, associations or NGOs, or on a case by case decision);
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 yearly 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 ETPN membership is the main decision making body for the Strategic Research and Innovation Agenda. The activities of members include:

- Facilitation of an environment to bring Nanomedicines to patients;
- Driving the definition and updating of the SRIA, overseeing its implementation;
- Yearly event on Nanomedicine;
- Election of the ETPN Chairs 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 ETPN.

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

This application should include the following:

- An Expression of Interest (EoI);
- A description about how the organisation will contribute to the ETPN'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 website address of the applying organisation

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

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 applying organisation is asked to sign an Offer of Services emitted by the ETPN Secretariat c/o VDI/VDE-IT committing his/her institution to the ETPN.

### **Membership of the Platform/Voting Rights**

Each member organisation is entitled to one vote that will be expressed by the member representative. Participation in the different working groups is possible without being a member, upon invitation of the WG Chair. Elections will occur during General Assemblies of the Platform (Yearly ordinary General Assembly, Extraordinary General Assembly). Electronic votes on the ETPN dedicated internet portal are allowed if required.

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**

Member organisations are free to change their representatives at the Platform by informing the ETPN Secretariat in writing about the termination of authorisation of the former representative and about the appointment of a new one. The successors would have to be individuals of high standing, in line with the

mentioned 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.

### Termination of Membership

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

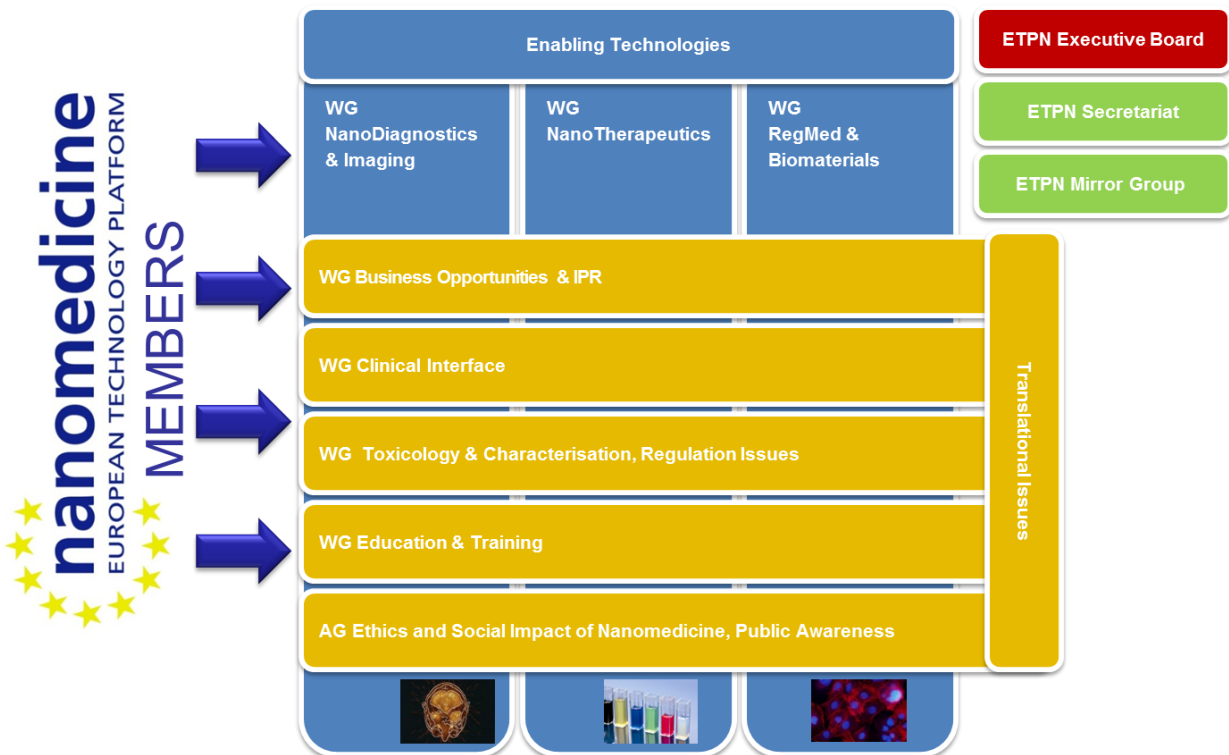
The first membership period is three years as defined in the Offer of services. The membership then is tacitly prolonged every twelve months, if not abrogated within the notification period of six months.

### 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 ETPN Secretariat is required. Member organisations may also send (a limited number of) observers to meetings of the ETPN but the ETPN Secretariat should be notified in writing.

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

## 3. Structure at 2013



## a. Executive Board

The Executive Board, a smaller executive and operational representation of the Platform, is 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;
- Prepares Platform meetings and decisions;
- Chairperson (or delegate) presides over Platform;
- Steers Working Groups and monitors their results;
- Approves new members 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;
- Takes decisions preferably by consensus (if not possible by majority voting);
- 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 ETPN or their delegates, the chairpersons of the Working and Advisory Groups (with voting rights); the General Secretary, the Mirror Group Chair and representatives of the European Commission with observer status (without voting rights).

- The current Chairman and Vice-Chairmen of the ETPN are detailed in Annex 2;
- The chairperson and vice-chairpersons are elected by the Platform. 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 an interim 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 ExBo meetings as observers.

## b. 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 on recommendation from the Executive Board and will come from industry for the technical working groups: nanodiagnostics,

nanotherapeutics and regenerative medicine. 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 members 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 ETPN members) to join WG activities and meetings.

#### **The current Set of Working and Advisory Groups (WGs/AGs) is:**

Science Working Groups:

- **Nanotechnology-based diagnostics, including imaging**
- **Nanotherapeutics: Nanopharmaceuticals and Drug Targeting**
- **Regenerative Medicine and Biomaterials**

These WGs will work out the content of the Strategic Research and Innovation 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 field and interface with professional associations in their respective fields.

Horizontal Issues related Working and Advisory Groups:

- **WG, Business Opportunities and Intellectual Property Rights**

This WG will work out rules for the treatment of intellectual property rights in research projects that develop out of the ETPN and support members with translation and business development issues and strategic partnerships with large companies. This WG will also liaise with the Nanomedicine Translation Advisory Board (TAB) once established.

- **WG Clinical Interface**

This WG will assure the link with clinical institutions, providing ETPN members with clinical requirements and unmet medical needs on one side and promote nanomedical technologies and actors towards end-users.



- **WG Toxicology, Characterisation and Regulation 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. Key issues for regulatory approval such as toxicology and characterisation are included in this WG's topics.

- **WG Education & Training**

This Working Group should address all educational issues aiming at facilitating comprehension and interactions between all actors in the nanomedicine value chain. This includes the definition of training courses for researchers and SMEs but also the dissemination of best educational schemes and best translational practices in collaboration with the Translation Advisory Board (TAB) once established and dedicated courses for all education levels (undergraduates, BSc, MSc, PhD, PostDoc).

- **AG Ethics and Social Impact of Nanomedicine, Public Awareness**

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.

Temporary Tasks Forces should complete or emphasise the scope of Working and Advisory Groups for a specific sub-topic and for a limited period.

### **c. 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 SRIA 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 elected by the Mirror Group members and will be a member of the Executive Board.

### **d. Secretariat**

#### **Responsibilities of the Secretariat**

- Organisational, secretarial and operational support to the Platform, the Executive Board, WGs, Sub-WG's, Annual Conference, etc.;
- Information and Communication centre for the ETPN, incl. Website;
- IT support;
- Financial matters of ETPN operations;
- Coordination, follow-up and consistency of WG activities;

- The General Secretary participates in the meetings of the Executive Board with observer status (without voting rights);

## 4. General Issues

### Costs and funding

- All participants cover their own costs.
- The ETPN budget will be managed by the Secretariat 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 Members. The membership fees per annum are presented in Annex 1 to the ToR.
- For potential additional tasks, funds will be sought through e.g. CSA projects.
- Individual R&D projects seek funding through regular public programmes at Community, inter-governmental, national and regional levels.

## 5. 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 Executive Board and the majority of votes of the Platform members. Only if both conditions are met, will the change be incorporated in the ToR.

## Annex 1: Membership fees per annum

Category	ETPN Membership	“NanoGold” Membership	“NanoPlatinum” Membership
Academia, research centres and associations	500 €	750 €	1.000 €
Healthcare Providers	1.000 €	1.500 €	2.000 €
SME < 15 ee	500 €	750 €	1.000 €
SME 16-50 ee	1.000 €	1.500 €	2.000 €
SME 51-250 ee	1.500 €	2.250 €	3.000 €
Industry > 250 ee	5.000 €	7.500 €	10.000 €

The “**NanoGold**” and “**NanoPlatinum**” Memberships include the ETPN membership as described in the ToR as well as following additional services:

	“NanoGold” Membership	“NanoPlatinum” Membership
<b>Services on ETPN related events</b>	Sponsorship in one event including exhibition space (poster / stand)	Sponsorship in all events including exhibition space (poster / stand) & one presentation slot on the event
<b>Increased visibility</b>	Display of logo / short presentation on different locations on ETPN website and promotional documents	Display of logo / short presentation on different locations on ETPN Website and promotional documents Further dissemination using ETPN communication channels when applicable (NanoMed TV, press articles)
<b>Services linked to the Translation Advisory Board (TAB)<sup>1</sup></b>	Free consultation hours	Extra free consultation hours

<sup>1</sup> As soon as the TAB is fully operational.

## **Annex 2: Current ETPN Chairpersons**

### **Chairman of the ETPN Executive Board:**

- Patrick Boisseau, Programme Manager Nanomedicine, CEA Leti, France

### **Vice-Chairman**

- Laurent Levy, CEO, Nanobiotix, France

**Last elections took place electronically in November / December 2012.**