



EU-LAC HEALTH 2nd Road mapping Workshop



Potential Models of a Support Structure of the Governance for EU-CELAC Cooperative Research on Health

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EU-LAC HEALTH has received funding from the European Union's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 281459.



Governance forms



- *An International organisation under International Public Law*
- *An special project managed by an International organisation*
- *An article 185 TFEU initiative*
- *An International Association under a National Law*
- *A Foundation*
- *A Consortium with no legal personality of its own*

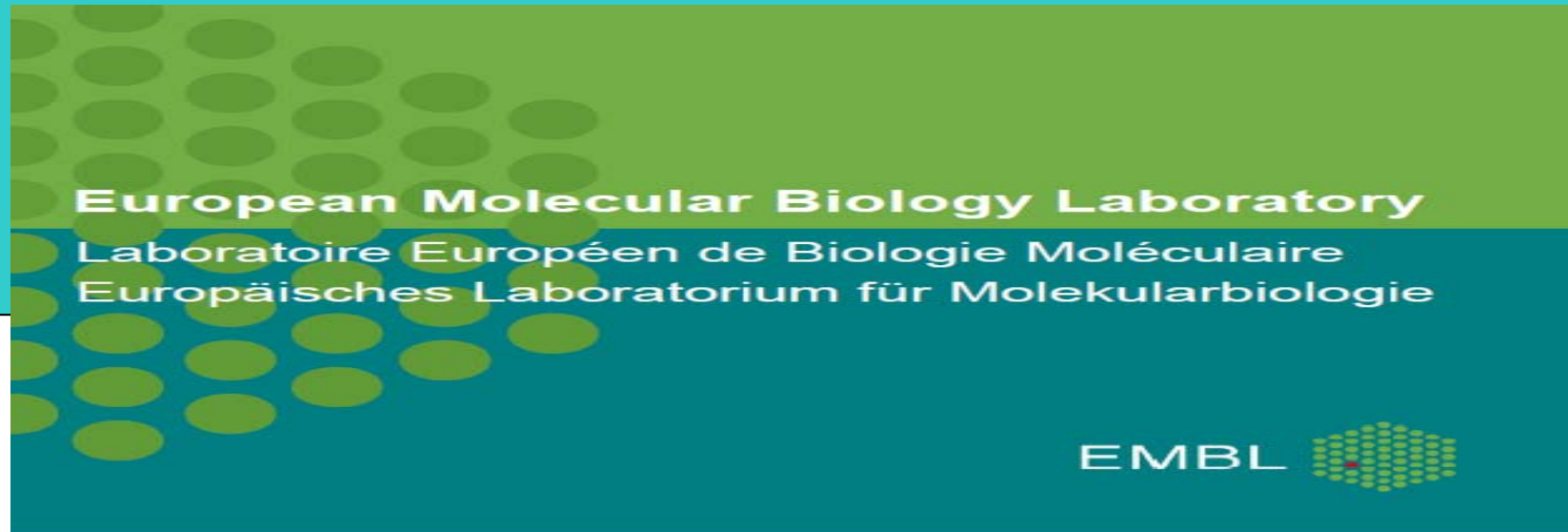


Governance legal forms



An International organisation under International Public Law, e.g.

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EMBL as an International Organisation

- Legal basis = International agreement between countries
- Headquarter agreement between the government of Germany and EMBL
- Comparable agreements between each outstation and respective country
- International legal personality
- Operates independently of national policies but under MS-control
- Privileges of EMBL as an organisation
 - Fiscal privileges (e.g. exemptions from value added tax, excise tax)
 - Exemption from national jurisdiction
- Privileges of staff working at EMBL
 - No tax on wages in order to attract the best scientists
- Liability limited to organisation instead of Member States



- Established in 1974
- Funded by 20 Member States
- Five sites in four countries



Legal forms of infrastructure entities – under International Public Law



It Implies an International Treaty

- Maturity enough of the political process at top level.
- Ratification / approval by National Parliaments (at least two year process).
- Use to come into force after reaching a threshold of countries' approval/ratification.
- Some countries never ratifies or do it after very long processes.



Governance legal forms



An special project managed by the another organisation, e.g.

- By the European Molecular Biology Laboratory

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An special project managed by the EMBL



It Implies International Consortium Agreement (ICA)

with some self governance without legal personality of its own.

- May also need ratification / approval by National Parliaments in some countries (at least two year process).
- Use to come into force after reaching a threshold of countries' approval/ratification. Some countries never ratifies or do it after long processes.
- At lest two year of preparatory process.
- Overheads charges.
- Member of the special project and members of EMBL may not be the same.
- No intuitive why to pay a contribution as a member of the “special project” and another as member. of EMBL



Governance legal forms



- *An article 185 TFEU initiative*

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Legal forms – under EU Law framework



.Article 185 TFEU initiatives

- EDCTP.
- ENMP.
- Eurostars.
- AAL.
- BONUS.



Legal forms – under EU law framework



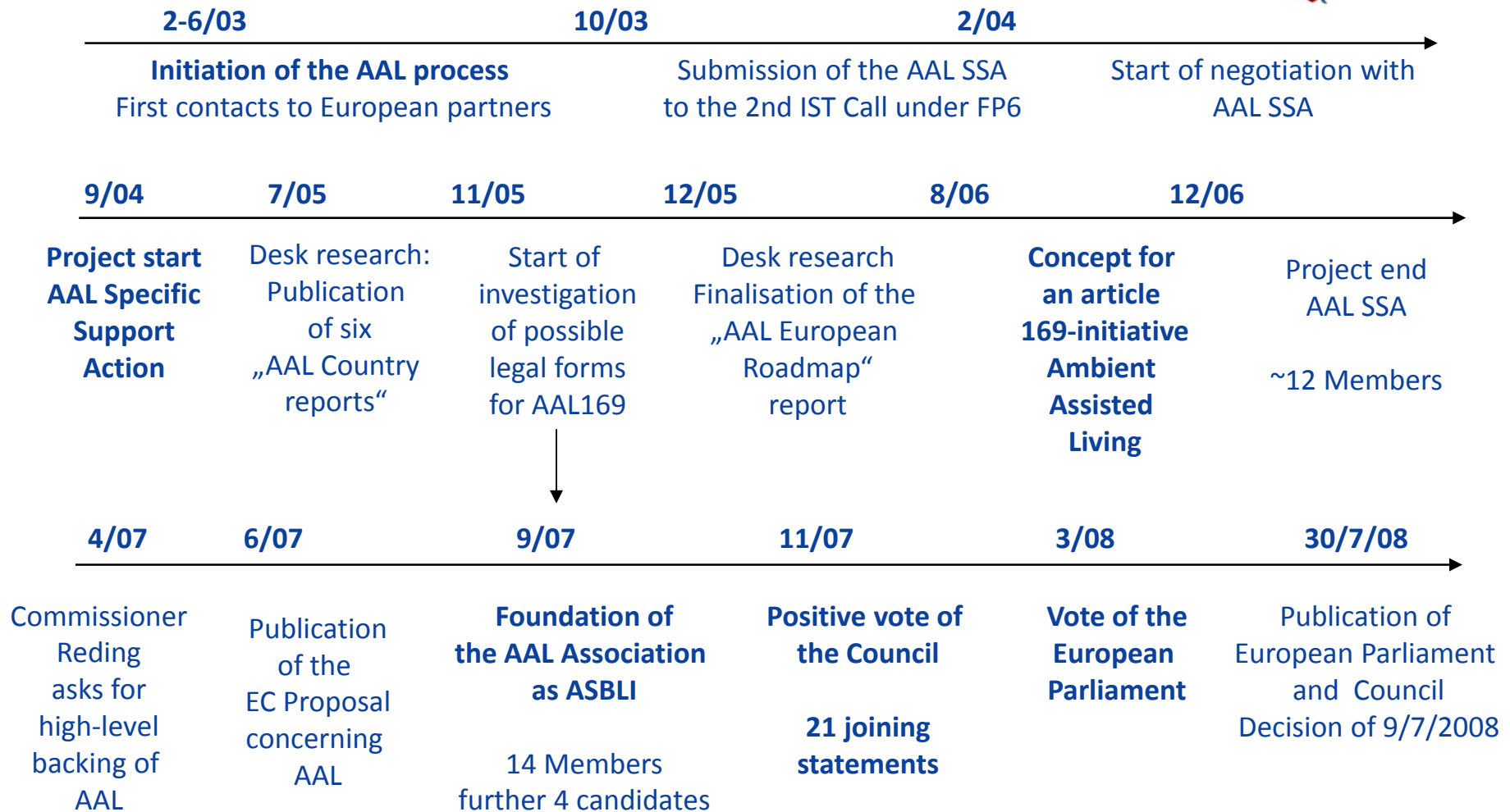
Article 185 TFEU initiatives, e.g.

- **EDCTP 1** - coordination and funding of national clinical trial activities in and in favor of developing countries in Sub-Saharan Africa.
 - Managed by an European Economic Interest Grouping (**EEIG**) 'under the corresponding EU regulation'.
 - **Two offices:** The Hague and Cape Town.
- **AAL** - coordination and funding of National applied research activities in active and assisted living in favor of ageing well.
 - Managed by an International Association under the Belgium Law (**ASBLI**).



AAL Roadmap

– so far under Art 185 ex 169 TFEU



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Legal forms - under EU Law



Art 185 TFEU initiatives. It implies

- Political process Mature enough at top level.
- At least two year legislative process at the European Parliament and the Council.
- The European Commission requests clear upfront funding commitment from the participating Associate and Member States to match EU **co-funding** prior to start the legislative process.
- Joint Undertaking management structure with legal personality.
- General and annual work programme grant agreement between European Commission and the Joint Undertaking management structure.
- Bilateral agreement between the Joint Undertaking management structure and each country mandated body.



Governance legal forms



- *An International Association under a National Law*

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Belgium Legal Framework

- A National Association or an ASBLI



- An ASBLI or a National Association that represents a specific sector of activity may be VAT exempt by the Ministry of Finance Theoretically is possible ..
- The scope of the National Association is limited to the Belgium territory, while an ASBLI has an important international engagement. **It is not appropriate for EULAC Health.**
- An ASBLI has to be established with a cheap cost by a
 - 1) notarial deed .
 - 2) recognition by the Minister of Justice (4 months).
- A National Association can be established by a direct private agreement without a notarial deed.



Governance legal forms



- *Foundation*

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Foundation under the Dutch legal framework

Main advantages

- The main body is the Board which is responsible for activities and assets.
- In principle not a profit-seeking entity.
- Allowed to make profits but with restrictions on the subsequent allocation of the profits.

Main disadvantages

- Participating States are jointly and a foundation is a legal entity without members or stakeholders. **As such this entity would not be appropriate for EULAC Health.**
- Established with a fixed capital to achieve a goal which is stated in the Statutes.
- No direct influence on management activities although indirect influence may be exercised through the appointment of Board members.



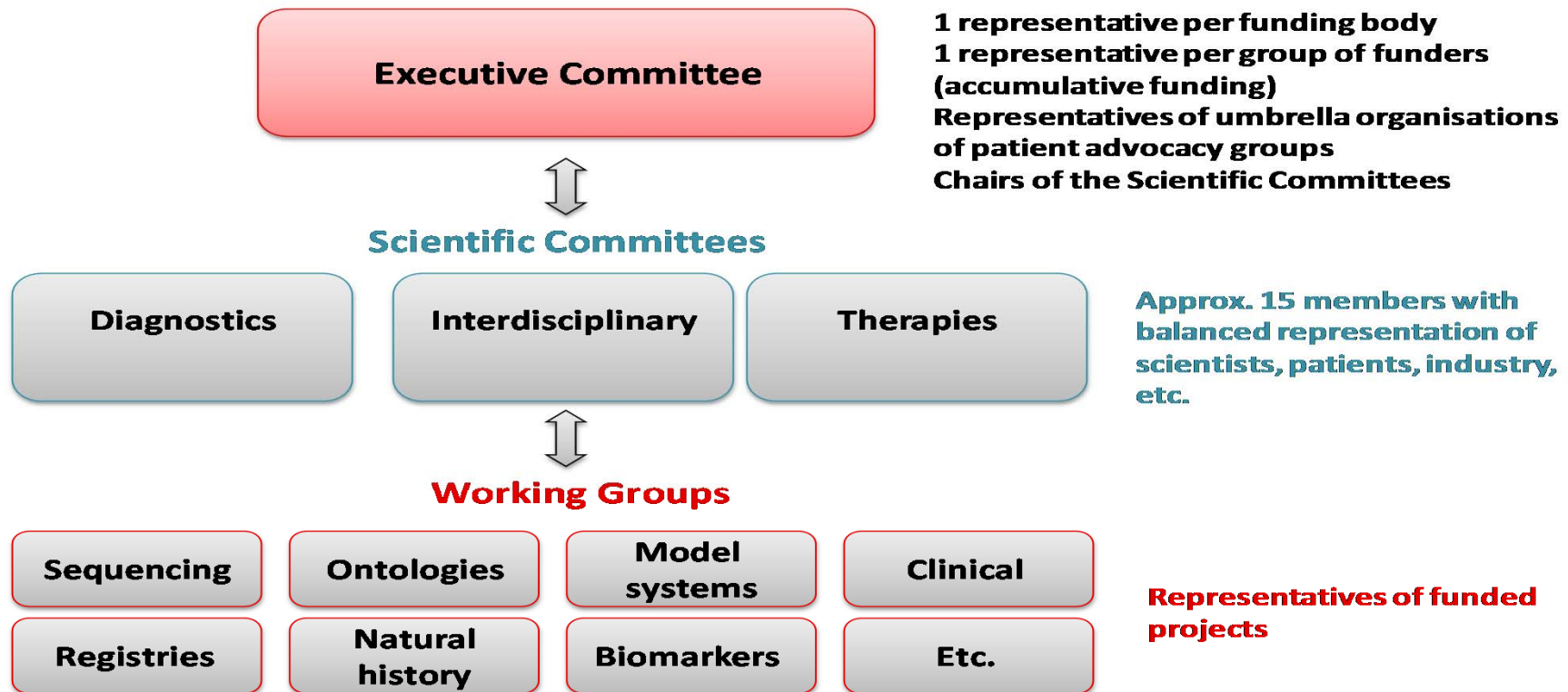
Governance forms



- *A Consortium with no legal personality of its own
e.g. ICGC, IRDiRC ...*



IRDIRC



A consortium with no legal personality of its own



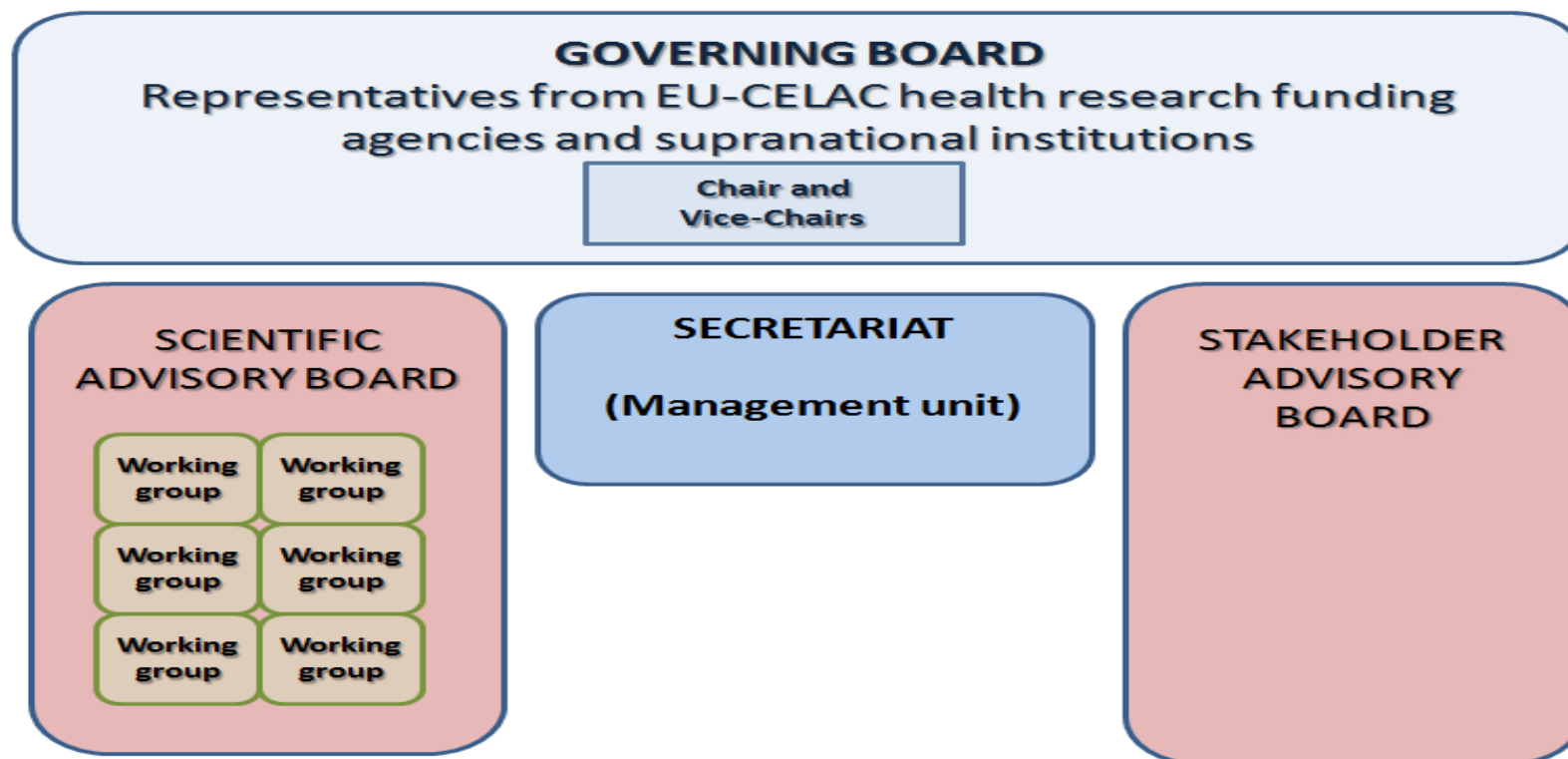
- Possibility of a common bi-regional framework for countries and [existing] instruments.
- Possibility of stakeholders' engagement .
- Capacity of evolving and encompassed with maturity.
- Flexible geometry.
- Allows progressive enrolment.
- Slim structure.
- Common R&D policy agreed by the consortium.
- Allows alignment of R&D programmes.
- National financial and administrative procedures applied.



A Consortium with no legal personality of its own - proposal



EU- CELAC- JOINT INITIATIVE ON HEALTH RESEARCH



A Consortium with no legal personality of its own



What it next.

- Relationship with the SOM working group on health within the new role of EU LAC Health as technical support.
- To draft the governance (membership, constituencies, commitments, ...).
- To circulate the governance draft for input.
- Suggested expected time in the task: 6 months.

In parallel

- To draft the validation consultation accordingly.
- To finish the selection of the target population of relevant policy makers to approach them to invite them to answer the questionnaire.
 - Proactive role of EU LAC Health partners is necessary.

To validate the governance just after

- Lessons learnt.

To invite Govs. to express interest [letter of intent] for membership.



A Consortium with no legal personality of its own



- A window of opportunity to try to get it ready before the end of EU LAC Health via fine tuning and try to launch a pilot action.
- To go ahead with everybody's complicity (different levels of interested parties)
- To be helpful and not painful



EU-LAC Health Partners



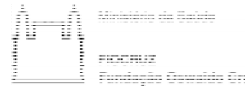
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