

# VAC4EU

VAccine monitoring Collaboration for Europe

**Patrick R. Mahy**  
for the VAC4EU planning group

Brussels, 6 March, 2019.

- **ECDC & ADVANCE Blueprint:**
  - different options for sustainability: tool box, network, project or just a hub
- **ADVANCE Steering committee**
  - September 2017: Consensus to explore hub model
  - January 2018: SC Bootcamp to define hub model outline
- **ADVANCE General assembly**
  - September 2018: consensus to establish VAC4EU as a non-for profit entity
- **VAC4EU planning group**
  - Writing of Statutes & bylaws
  - Developing logo, website content
  - Searching funding opportunities

## Organizational characteristics

- Legal entity
- Non-for-profit international association (Belgian law)
- VAC4EU statutes have to be signed by the King Philippe (royal decree)



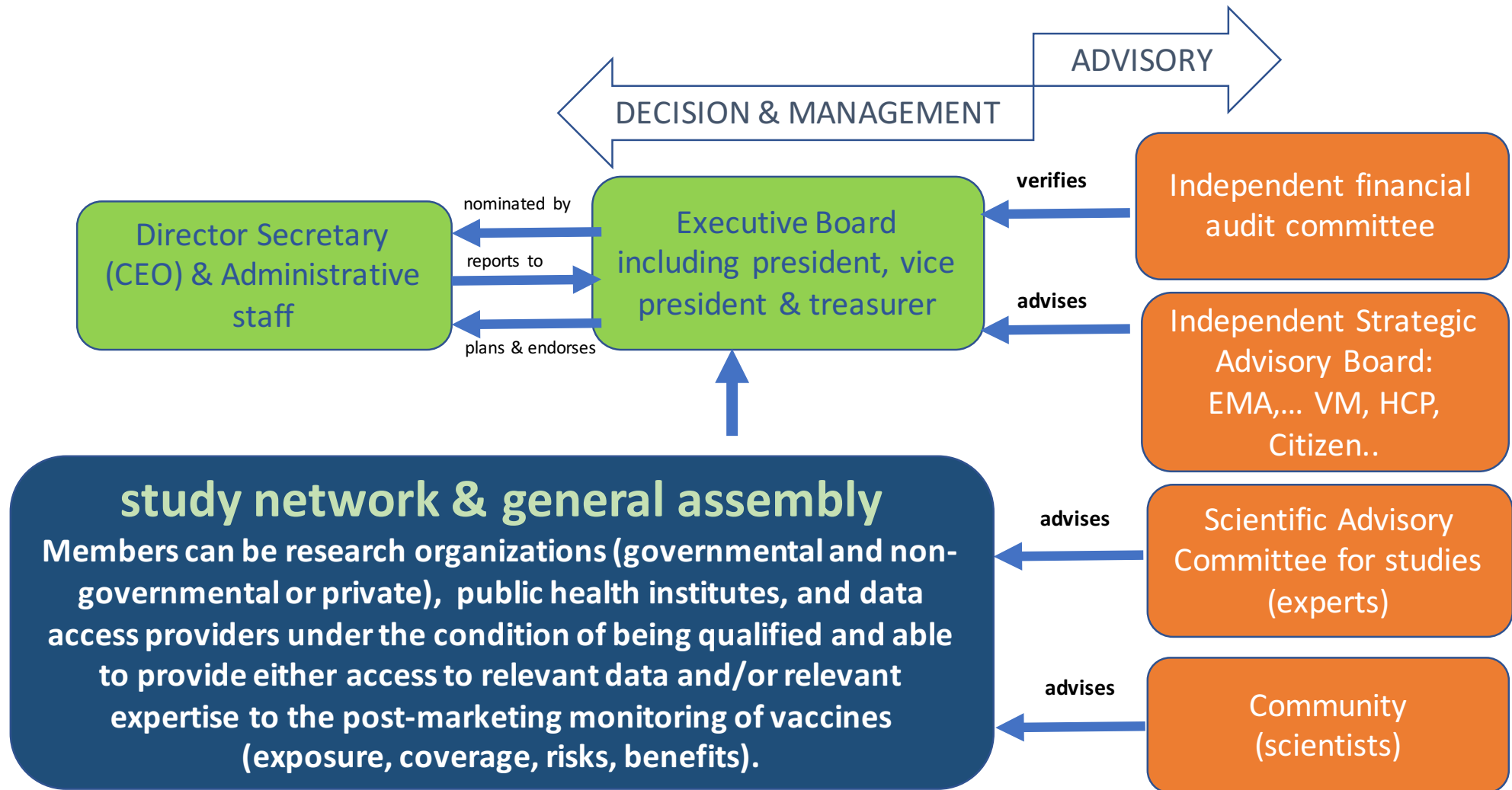
## Aim

- To enable, coordinate and accelerate the generation of best actionable real world evidence on vaccine coverage, benefits and risks.

## Objectives

- To perform studies answering to calls (study network)
- Implement a European partnership able to respond to vaccine related questions
- Stimulate continuous methodological developments (community)
- Train and provide rapid access to a unique vaccine expert network
- Build synergy and consensus between stakeholders
- Support the adoption of best practices
- Ensure sustainability of the EU platform

## Governance structure (proposal)





### Study network & general assembly

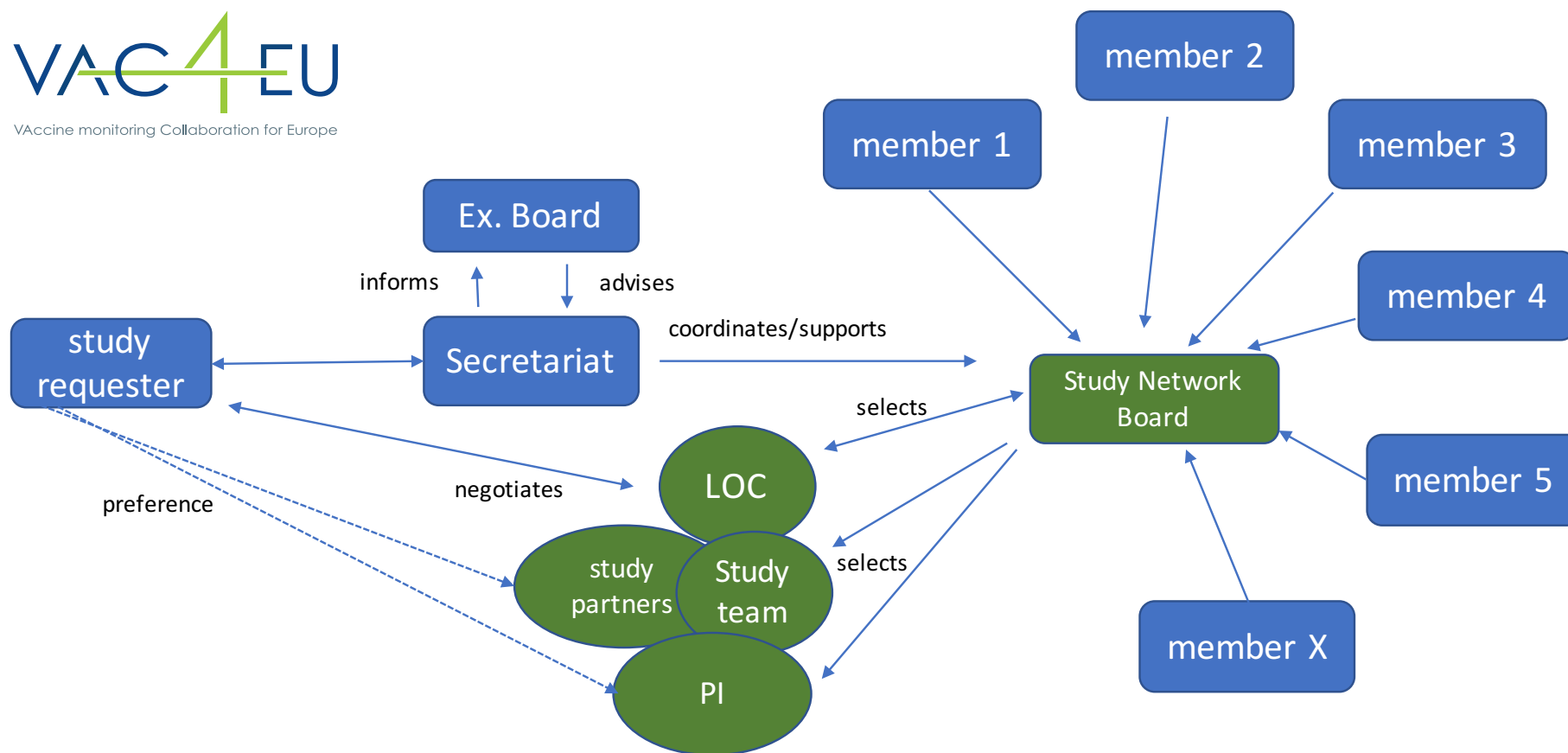
- Run and update database characterization
- Conduct collaborative vaccine coverage, benefit, risk and benefit/risk studies
- Use VAC4EU platform, facilities, best practices and procedures for studies
- To elect the executive board members
- To approve major VAC4EU decisions and annual accounts.

### Secretariat

- Administer and promote VAC4EU
- Support Executive Board & Study Network and all committees plus community
- Identify & characterize new data sources and calls for studies
- Maintain and seek new funding & collaborations
- Organize online training

### Executive Board

- Guide the VAC4EU Association
- Promote VAC4EU locally and internationally



## DECISION MAKING FOR STUDY CONDUCT

Activity	Study requester	Ex.Board	Secretariat	Principal investigator	Study network board	Lead operating center (LOC)	Study partners	Study team
Study request	Sends request		Verifies					
Expression of interest			Coordinates		Respond			
Study outline	Provide		Coordinates		Comment			
Approval outline	Endorses	Informed	Coordinates		Endorses			
PI selection	Preference	Approves	Coordinates	Provide interest & CV	Select			
LOC selection	Preference		Coordinates	Endorse	Select	Provides Lol, experience & cost estimate		
choice of CoC	Requests	Review of Dol	collects Dol		Provide Dol and CoC preference			
Data sources	Preference		Coordinates	Advise	Advises & Eol	Negotiates & decides		
Study team			Coordinates	preference & Endorses		Endorse	Endorse	Endorse
Protocol approval	Comments & approves		Supports	Develops & approves		Coordinates & approves		Develop & sign
Budget	Comments & approves		Supports			Coordinates & approves	Cost estimates & approve	
Contract	Signs		Supports			Negotiates & contracts	Sign subcontract	
Execution protocol	Informed		Supports	Coordination		Coordination		Conduct
Reporting	Reads and comments		Supports	responsible		Coordinates & delivers		Write & approve



## TRAINING ACTIVITIES (DRAFT)



### Researchers & data scientists

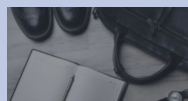
Vaccinology principles, Study designs, Health data characteristics and assessment

Protocol writing, statistical analysis plans for distributed analytics, programming for distributed analytics, development of visualization tools



### Health care professionals

Understanding monitoring of benefits and risks of vaccines. How to communicate with hesitant parents. How to interpret real world evidence and where to find it. How to stand trial



### Regulators

The robustness of VAC4EU real world evidence generation on vaccines, how to assess?



### Citizens

How are vaccines marketed and monitored?

Where to find reliable information on the safety and benefits of vaccines? How to weigh benefits and risks?

## Source of financing

- Membership fees
- Research Grants (e.g. H2020, Health call, ECDC or EMA tenders)
- Donations & support
- Service fees (e.g. training, access to data characterization, access to platform)
- Overhead on studies conducted through VAC4EU study network (reimbursing matchmaking efforts of secretariat)

## Cost initially

- Website, legal and setting up: covered by ADVANCE sustainability efforts
- Secretariat 1.5 fte (150 K per year), persons may be outsourced by member organizations
- Platform for datasharing (30-50 K per year, depending on use)

How to become a member now?

Apply to ADVANCE CT (Miriam, Patrick, Vincent, Eva)

Want to know more?

Visit

[www.vac4eu.org](http://www.vac4eu.org)