EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 4:
Looking towards the future: Brainstorming on funding mechanisms for PAS

Example: Collaborative vaccine studies

Presented by Xavier Kurz

ADVANCE

EUROPEAN MEDICINES AGENCY

Accelerated Development of VAccine beNefit-risk Collaboration in Europe

- Public-private partnership created in the framework of the Innovative Medicines Initiative (EC+EFPIA)
- Coordinated by Erasmus University + GSK
- Public health agencies, academic institutions, regulatory authorities, vaccine manufacturers

Objective:

To create an infrastructure and a sustainable framework for vaccine benefit-risk monitoring in Europe

WP1: Best practice Guidance

- *Code of conduct:* principles for collaboration between study participants
- *Quality management*: "minimum" quality management principles to be defined
- *Governance models:* roles & responsibilities, mechanisms of interactions
- *Communication recommendations:* how to communicate about vaccines safety and results of vaccine studies

WP2: Synergies with other projects

WP3: Data sources

WP4: Methods

WP5: Proof-of-concept studies

WP1 / WG3 Governance models

EUROPEAN MEDICINES AGENCY

Objective:

- to identify a few “typical” governance models for vaccine studies involving several stakeholders
- to provide recommendations on governance aspects
- to provide recommendations on which model(s) could be applied in different situations

Based on experience of studies that worked well or did not work well

Identification of typical scenarios (still on-going)

Scenarios (1)

A public health institute intents to conduct a study to evaluate the effectiveness of a vaccine within a vaccination program.

Hypothesis:
Operational support needed; PHI data owner; vaccine effectiveness to be measured is not brand-specific.

A public health institute intents to raise awareness about the benefits of its vaccination program. The vaccine manufacturers who provide the vaccines are willing to support this initiative.

Hypothesis:
Involvement of several MAHs; not brand-specific.

Scenarios (2)

EUROPEAN MEDICINES AGENCY

A vaccine manufacturer intents to conduct a study to assess the burden of disease to a candidate vaccine and use a large public health database it has no direct access to.

Hypothesis: Academia/CRO can have access to public health database; brand-specific.

A vaccine manufacturer intents to conduct a study to generate more evidence about the effectiveness of its vaccine in routine use.

Hypothesis: MAH can generate its VE own data or can use data from surveillance system; brand-specific.

Scenarios (3)

Due to concerns regarding the safety/effectiveness of a vaccine, a regulatory authority requests the vaccine manufacturer to investigate the safety/effectiveness/benefit-risk profile of its vaccine.

- Legal responsibility for the vaccine manufacturers
- Study protocol and report to be endorsed by regulators
- Vaccine manufacturers required to revise protocol/report
- Brand-specific investigation
- Secondary use of data vs. primary data collection
- For some public health institutions, legal/public perception issues to involvement of vaccine manufacturers

Which governance model(s) could allow participation of vaccine manufacturers?

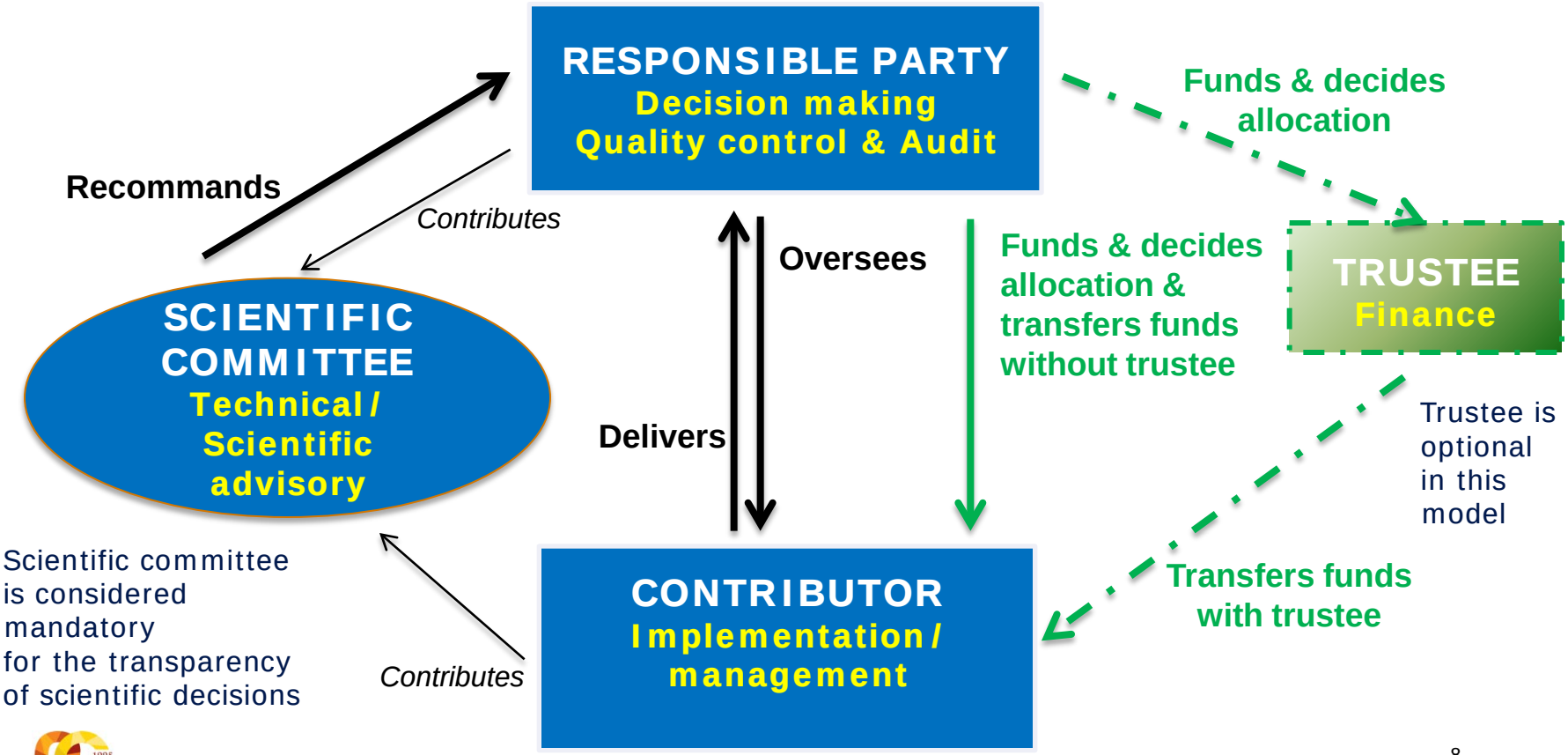
EUROPEAN MEDICINES AGENCY

Five basic functions in all studies

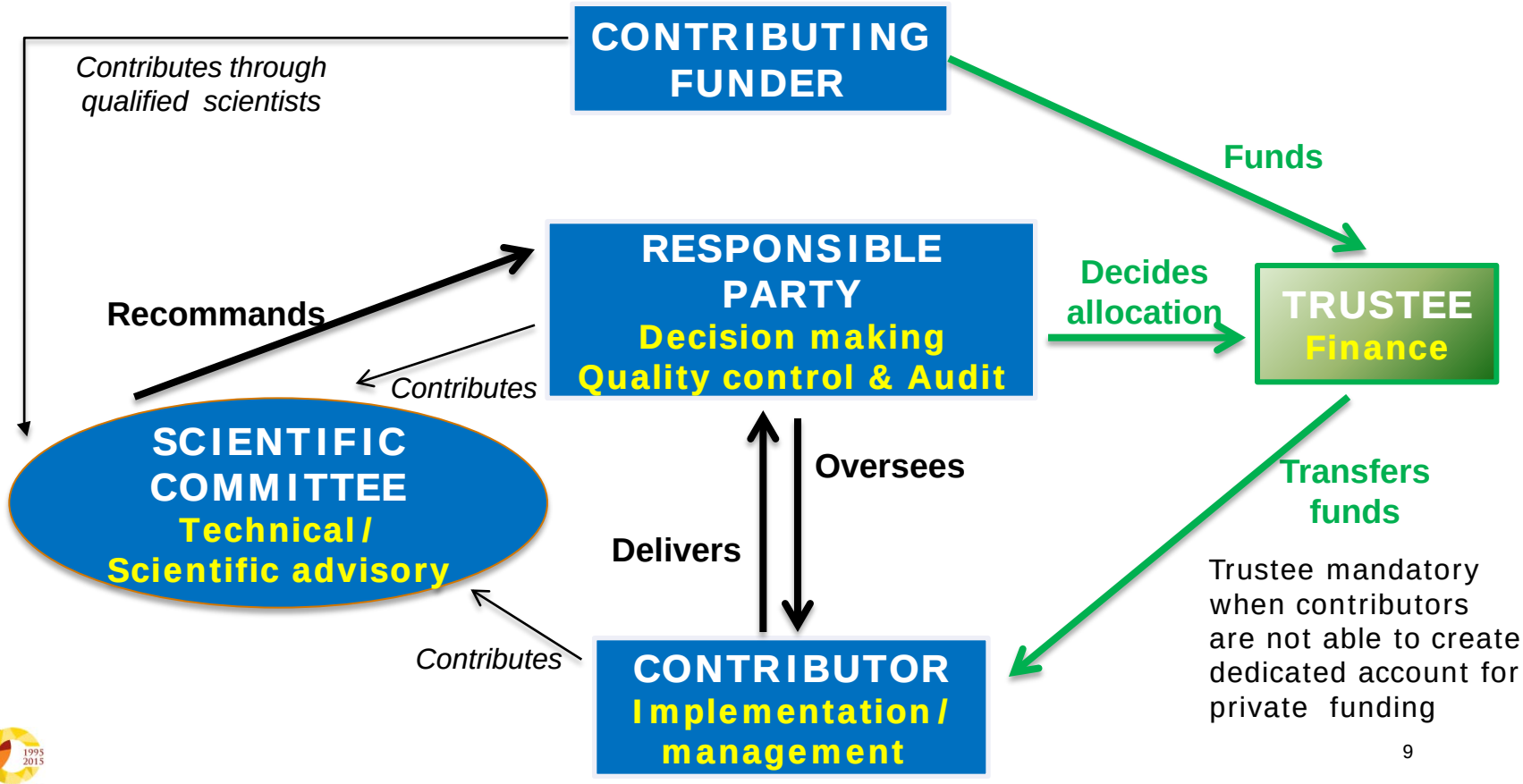
- Decision-making
- Implementation/management
- Technical/Scientific advisory function
- Quality control & audit
- Finance

R&R for each function should be clearly identified at the start of the study.

Model 1: Study self-supported by responsible party (incl. with grant)

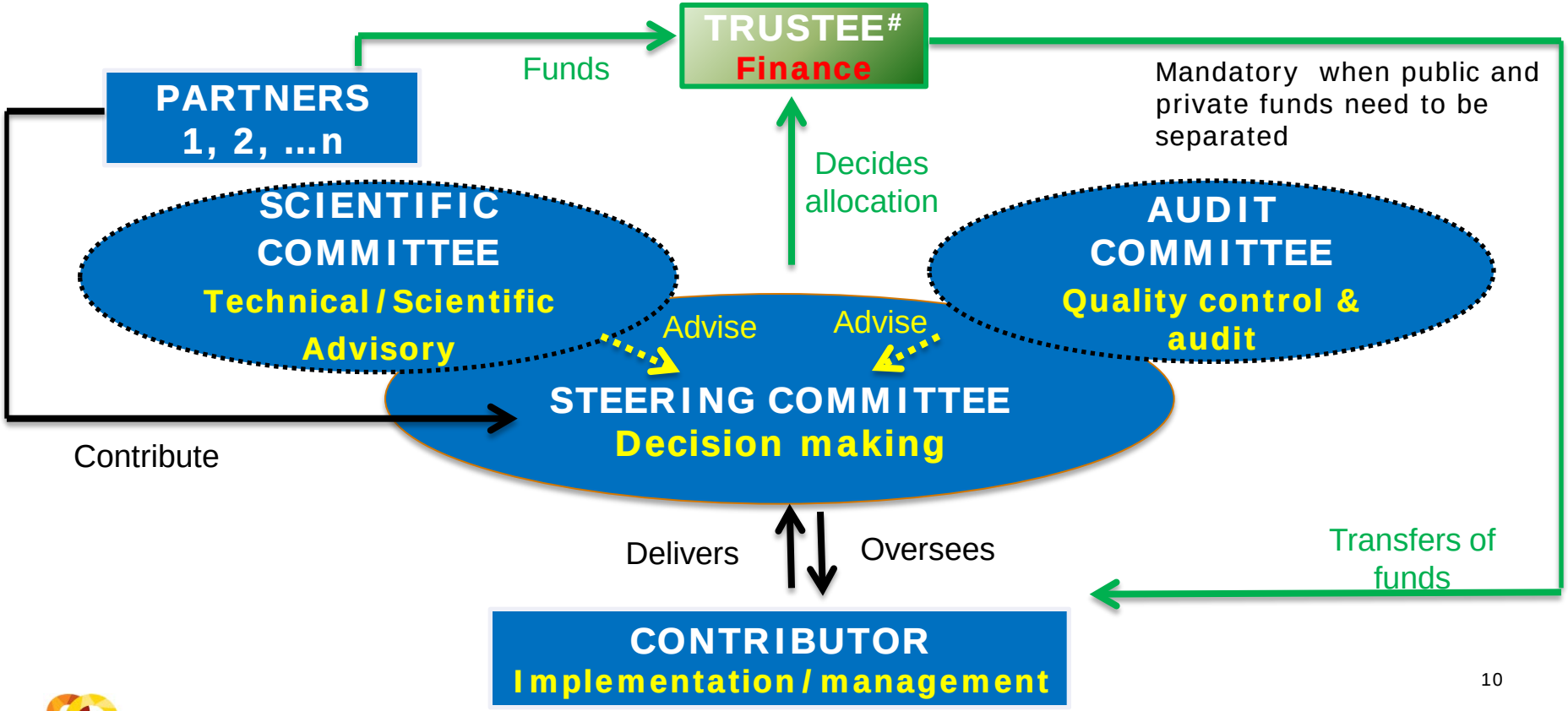


Model 2: Collaboration with contributing funder



Trustee mandatory when contributors are not able to create dedicated account for private funding

Model 3. Partnership with shared funding/tasks



Due to concerns regarding the safety/effectiveness of a vaccine, a regulatory authority requests the vaccine manufacturer to investigate the safety/effectiveness/benefit-risk profile of its vaccine.

Issue: how to accommodate different constraints

- Vaccine manufacturers have legal obligations
- Regulators want to ensure best possible design for research question
- Some public health institutions may not interact with vaccine manufacturers
- The public is concerned by possibility of conflicts of interest

Model 1 *(collaboration self-funded by the responsible party)*: Study conducted by Academia/CRO – VM is the decision maker

Model 2 *(collaboration with contributing funder)*: VM provides funds and contributes to the project – PHI is the decision maker

Model 3 *(partnership)*: Study conducted jointly by PHI and VM through a CRO/Academia

Model	1	2	3
Responsible party	VM	PHI	PHI & VM
Contributing funder	VM	VM	VM
Restricted /partial data access	Academia/CRO VM	PHI	PHI & VM
Results ownership / co authorship	VM	PHI co-ownership/authorship possible	PHI & VM
Comments	Most challenging situation: model 2 preferred by PHI for public trust in safety results and model 3 preferred by VM due to accountability in regulatory context		

Some suggestions from public health authorities present in ADVANCE:

- Regulator involved in steering committee to provide assurance to the public about lack of conflicts of interest
- Regulator liaises directly with public health authority / academic institution
- Choice of contributors for data collection and analysis independent from vaccine manufacturer (/regulator)
- Only centres accredited at national level allowed to participate in regulatory studies,
- etc…

Other suggestions?

Thank you for your attention

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**