



EUROCAB PRACTICAL AND FINANCIAL ASPECTS

EMM

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EURODIS.ORG



Why should CABs be part of the EUROCAbs programme?

Experience: CABs benefit from experienced guidance on how to operate a CAB and do it well – we have experience!

Training: *CABs benefit from EURORDIS training (5 at Summer School each year, Winter School, ad hoc trainings)*

Credibility: CABs benefit from EURORDIS credibility and strong governance

Standard: EuroCAB as a Patient Engagement standard? CIOMS (GPEP)

Up-to-date: CABs will be aware of initiatives along the products life-cycle (e.g. STAMP, Women CT and DITA, TransCelerate (700-100)...)

Visibility: CABs become more visible! *EUROCAbs website being designed*

Soon to come: your membership agreement

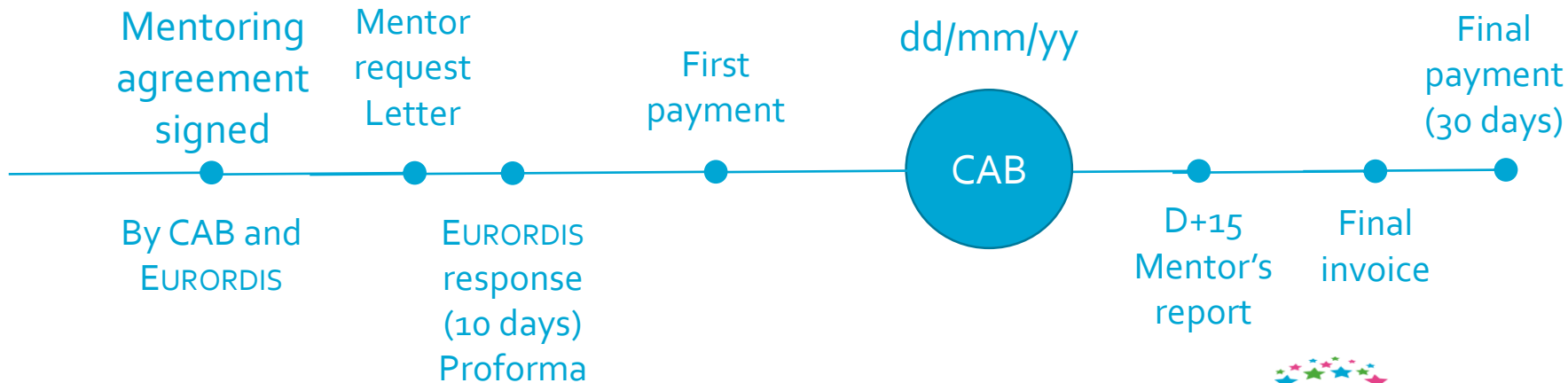
- For all CABs (autonomous, mentored, hosted)
- A document that
 - Explains the EuroCAB programme: benefits of joining the programme, respective roles and responsibilities, financial arrangements
 - Explains the CAB seal (check list after 1 or 2 years of operation)
 - Includes the guidelines and other materials and templates (CAB member job description, Code of Conduct, DoI...)
- Signed by the organisation representing the CAB on behalf of CAB members, and by EURORDIS

For those asking for the mentoring programme

- For a limited period (typically 2 years)
- As part of a specific mentoring agreement
- Describes respective roles and tasks, and financial arrangements

To cab@eurordis.org, with:

- the date of the session and its duration
- the desired number of days for the CAB mentor



Open call for volunteers

- Principles
 - Openness
 - Inclusiveness
 - Transparency
- Call to members, social networks, members or not of an organisation: CAB members are preferably connected to other patients
- Job description? Appointment procedure? Not enough candidates? Can new members join at any time?
- (Can trial participants be member of a CAB?)
 - (one convincing argument against heard so far: risk of unblinding the treatment arm)
- Renewal? Training?
- Audit: to come to your office and see how potential candidates were contacted

Agendas and members made public

- Agendas
 - Public on the Register when created (“The Gate”), and your own media
 - Also available on request
 - Contain no confidential information (you can have a more detailed agenda for internal purposes)
- List of members
 - Published on the Register, and your own media
 - Also available on request
 - Sponsors can inform trial participants about the CAB and how to contact its members (via investigators and/or via the information letter for consent)

Members...

- Should be from different countries
- They should be member of an organisation, not unaffiliated individuals
- CAB organisations should adhere to the [Code of Practices Guiding the Relations between Patients' Organisations and the Healthcare Industry](#) signed by organisations that are member of the Patents' and Consumers' Working Party at EMA
- There is also a Declaration of Interest that all members need to sign
- They should commit to a minimum of 2 face-to-face meetings a year and other e-meetings over at least two years (from experience: 2 per month!)

Chair/co-chair

- Plan, prepare and chair the CAB meetings ensuring:
 - A balance is struck between time-keeping and space for discussions
 - Everyone's voice is heard and helps that to happen
 - Business is dealt with and decisions made
 - Decisions, actions and deliberations are adequately minuted
 - The implementation of decisions is clearly assigned and monitored
- Ensure adequate support and supervision arrangements are made for the administrative head, the mentor and any other staff/volunteers
- Ensure that a successor is found before the term of office finishes

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Finances



7. Pricing

For one CAB session, the CAB mentoring activities will amount to a maximum amount of 14 000 € unless otherwise agreed to by both parties via the PCR procedure.

This figure is based on an average of 12 days of professional services for one CAB session including all activities included in the Workload Estimate paragraph. This amount is based on the following functional/rate structure.

Item Description	Total	Daily Rate	Number of days
Travel and accommodation	710 €		
CAB session mentoring	8 400 €	700	12
E-meetings	1 000 €		
EUROCAB programme membership fee	3 890 €		
TOTAL	14 000 €		

8. Payment Procedures

EURORDIS will be paid:

- 60 % of the total amount within thirty (30) days after reception of the written confirmation mentioned in article 3;
- 40 % of the total amount within thirty (30) days after the reception of the invoice.

Payment shall be made by bank transfer, referencing this CAB Agreement Number (001) to the account indicated below:

Financial arrangements

Type of CAB	EuroCAB membership fee (<u>per session</u>) paid by the organisation signing on behalf of the CAB
Autonomous	1,500 €
Mentored	14,000 € for up to 12 mentor days, to be adjusted if more
Hosted	- (all costs paid from sponsors to EURORDIS)

NB: there will be a revision.

CAB to pay directly all travel and accommodation costs for the mentor (lump sum of 710 € not enough) and some hotel rates are not in line with EURORDIS practices

Estimate your budget: indicative only, depending on number of days, participants...

Item	Per participant	Total 8 participants, 1 mentor, 2 days, 450€ compensation fee/day	Total 12 participants, 1 mentor, 2 days, 600€ compensation fee/day	Total 16 participants, 1 mentor, 3 days, 600€ compensation fee/day
Travel	350 €	2,800 €	4,200 €	5,600 €
Hotel (1 night), subsistence	180 €	1,440 €	2,160 €	5,760 €
Room renting, equipment		1,050 €	1,050 €	1,575 €
Catering	50 €	450 €	650 €	1,125 €
Compensation time spent	450 – 600€	7,200 €	14,400 €	28,800 €
Administration costs	1,250 €	1,250 €	1,250 €	1,250 €
Overheads	20 or 25%	2,838 €	5,928 €	11,028 €
Total		17,028 €	29,638 €	55,138 €
EUROCAB mentoring		10,110 €	10,110 €	10,110 €
EUROCAB programme		3,890 €	3,890 €	3,890 €
Grand Total		31,028 €	43,638 €	69,138 €
Cost per sponsor if 2		15,514 €	21,819 €	23,045.83 €*

*: if 3 sponsors

Options		
Minute taker (1,920 €)	Technician (960 €)	External trainer (1,000€)

Financial flow

- If the total cost of a session is 40 000 € including the 14 000 € for the Mentoring Programme, then the CAB invoices sponsors for the total amount of 40 000 €
- Sponsors pay a total of 40 000 € to the CAB (there can be 1,2,3.. Sponsors, the total amount to be divided according to the number of sponsors)
- The CAB pays 14 000 € to Eurordis for the Mentoring Programme
- In total the sponsors cover all costs, including the 14 000 € the CAB pays to Eurordis

Fees cover:

- Mentor days (\approx 12 days)
- Trainings (à la carte / e-learning modules) and/or ad hoc (EURORDIS staff or fees for external experts)
- Annual meeting of CAB chairs
- Training of new mentors (attendance of sessions as observers)
- Time for the development and update of guidelines, templates, materials
- Creation and maintenance of the register
- Communication materials (publishing costs)
- Evaluation / impact strategy, liaison with PFMD, Paradigm...
- CAB Seal costs (on site visits)
- Coordination time
- Overheads (Other costs and other Eurordis staff (finance team, communication team))

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- Work in progress

Guidance

- On how to operate a CAB
- On travel, accommodation, financial compensation
- Code of Conduct for Cab members
 - Declaration of Interest



How to operate a CAB? headlines

- Creation of the CAB: Identification of potential CAB members, Composition of the CAB, CAB membership renewal
- Working with public research
- Deciding which developers to work with
- Preparing the first meeting: Location, Expense management, per diems, Indicative Costs per meeting
- Preparing the meeting: Charter on Clinical Trials, Memorandum of understanding (MoU), Mentor, Scientific Secretariat, Chair & Co-chair, Administrative Secretariat
- Liaison with Sponsor / Developer
- Agenda and documents
- Training needs
- Sponsor's delegation
- A meeting step-by-step
- Decisions, Reporting, Communication with the trial participants
- Public communication
- Communication between CAB members
- Confidentiality
- Quality assessment and impact

Travel, accommodation and compensation for time spent

• 1

- Economy class travel
- Exceptions exist for business class travel
- By car reimbursed when the most economical and distance to session < 200 km

• 2

- Accommodation: booked and paid by CAB secretariat
- non-luxury / moderately priced hotels

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- Insurance: The CAB's travel insurance covers CAB members only, and an accompanying person if authorised

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- Time spent: 450 to 600 € per meeting day, half this for e-meetings
- To the discretion of the CAB
 - Tax consequences for individuals

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- Miscellaneous and how to claim expenses

Thank you for your attention

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CAB member job description

- Clinical trial participants, other patients and potential patients, parents and guardians and carers can candidate.
- They should have the specific condition for which the technology developed, be a parent of someone living with the disease, or be a member of an organisation dealing with the condition
- Patient representatives who are applicants, members or observers in scientific committees of the European Medicines Agency or in Health Technology Assessment bodies, or their management boards cannot be either a member or mentor of a CAB, due to conflict of interests.
- Desire to work fairly intensely in research, want to share ideas, speak English relatively well, and volunteer to be more and more active as time goes on.

Chair roles and qualities

- EuroCAB interlocutor
- Represents the CAB vis-à-vis external contacts
- Qualities
 - A willingness to help lead the CAB
 - Possess tact, diplomacy and powers of persuasion
 - Possess relevant knowledge
 - Have the relevant skills to run a meeting well
 - Good leadership skills
 - Good communication and interpersonal skills
 - Impartiality fairness and the ability to respect confidences
 - Ability to ensure decisions are taken and followed-up