

The logo for the European Bioanalysis Forum (EBF) is located in the top right corner of the slide. It consists of the letters 'EBF' in a white, sans-serif font. Below the letters is a white, curved line that starts under the 'E' and ends under the 'F', resembling a stylized arc or a partial circle. To the right of this arc, the words 'European Bioanalysis Forum' are written in a smaller, white, sans-serif font, stacked vertically.

European
Bioanalysis
Forum

European Bioanalysis Forum

EBF Organisation:
Getting Ready for the New Decenium

Presented by Peter van Amsterdam at:

EBF 3rd Open Symposium

1-3 December 2010, Barcelona, Spain

EBF – History - 1

Oct 12th 2006 – Brussels

- In a “EU-DVDMDG type meeting”, over 10 EU companies, together with some CROs, joined to discuss mostly ISR in an open and stimulating atmosphere.
- At the end of the meeting a number of companies, formally launched the idea of a broader European BA Organization

EBF – History - 2

Nov 10th 2006 - Berlin

- 1st EBF meeting at Schering (currently Bayer Schering Pharma)
- 12 companies signed up to join EBF
 1. Merck-Serono
 2. Boehringer-Ingelheim
 3. Novartis Pharma AG
 4. F. Hoffmann-La-Roche
 5. NV Organon
 6. Shire Pharmaceuticals
 7. Schering Pharma AG
 8. Sanofi-Aventis Deutschland GmbH
 9. Astellas
 10. AstraZeneca
 11. UCB
 12. Johnson & Johnson
- Agreement on the name: European Bioanalysis Forum
- Groundrules of EBF were discussed and agreed

EBF members – 2010

1. Abbott
2. Actelion Ltd
3. Active Biotech
4. Almirall
5. Astellas
6. AstraZeneca
7. Bayer Schering Pharma AG
8. Boehringer-Ingelheim
9. Eisai
10. Ferring Pharmaceuticals A/S
11. Grünenthal GmbH
12. GSK
13. F. Hoffmann-La Roche
14. Johnson & Johnson
15. H. Lundbeck A/S
16. Merck&Co
17. Merck Serono
18. Novartis Pharma AG
19. Novo Nordisk
20. Nycomed
21. Schering-Plough
22. Orion Corp. Orion Pharma
23. Pfizer
24. Sanofi-Aventis
25. Servier
26. Shire Pharmaceuticals
27. Solvay Pharmaceuticals
28. UCB Pharma

EBF: Scope

- Our focus is bioanalysis within pharmaceutical R&D
- Bioanalysis is defined as:
 - quantification of small and large MW drug and metabolites in body fluids and tissues
 - quantification of PD and safety biomarkers amenable to conventional bioanalytical techniques (binding assays, chromatographic assays)
 - bioanalytical characterization of biologicals

EBF – how were we organized ?

Ground rules:

- only Pharma R&D companies can become member
- each company assigns 1 representative (and a deputy) to the EBF.
 - the representative is single point, represents all EU-BA areas of the member company.
 - the deputy replaces the representative when he/she cannot attend.
 - Meeting attendance is mandatory for representative or deputy after 2 missed meetings.
- we don't:
 - exchange portfolio or IP information
 - allow advertisements of members or invites
- **Steering committee:**
 - 5 member companies assigned for 2 years
 - communicate on behalf of the EBF on EBF matters
- Internal discussions within EBF aim to recommend or influence opinions/procedures towards our members, business partners, regulatory bodies,.....

EBF – how were we organized ?

Steering committee meetings

- Steering committee members only
- Frequency and venue:
 - 1x per year in Berlin + adjacent to closed and open meetings

Closed meetings:

- For member companies only
- Frequency and venue:
 - 2x per year (Winter and Early Summer - 1.5 day) in Basel area

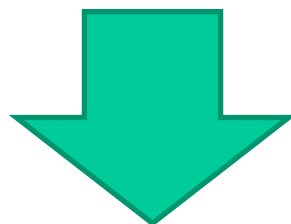
Open Symposia:

- Including CRO, regulatory bodies, academia, vendors, others
- Frequency and venue: Yearly (December – 2+ days) in Barcelona

Participation to other meetings on BA topics

- Non profit related
- Examples are: AAPS – BSAT – FABIAN – GMP France – RPS – CVG - ...

In 2008, EBF saw the need for an
Interest Group for Macromolecules



EBF-IGM

EBF-IGM members - Sept. 2010

1. Abbott
2. Astellas
3. AstraZeneca
4. Bayer Schering Pharma
5. Boehringer-Ingelheim
6. **Crucell**
7. Ferring
8. **Centocor (J & J)**
9. Lundbeck
10. Merck Serono
11. **Micromed**
12. Novartis
13. Novo Nordisk
14. Nycomed
15. Pfizer
16. Roche
17. Sanofi-Aventis
18. Shire
19. Solvay Pharmaceuticals
20. UCB
21. Schering-Plough

EBF-IGM: Scope

Macromolecules

- PK assay evolution: Non-GLP vs. GLP
- Technology platforms for ELISA and cell based assays: Automation
- Quantification of macromolecules by LC-MS/MS
- Quantification of the "free drug"
- Regulations for macromolecules
- Influence of Immunogenicity on PK data
- And many more....

Biomarker

- Validation
- Validity

EBF-IGM: How were we organized?

Steering committee (SC) meetings:

- SC members only (2 EBG-IGM SC members are also EBF SC)

Closed meetings:

- For member companies only
- Frequency and venue:
 - 2x year (adjacent to EBF closed summer-meeting and open Symposium)

Open meetings:

- No separate open meeting

Participation to other meetings on BA topics:

- Non profit related
- Close connection to AAPS LBABFG SC as contributors to NBC

EBF and EBF-IGM: How we do work?

EBF and EBF-IGM

How we do work

- Direct (email) interaction between members on bioanalytical issues
- Mini-surveys initiated by a member
- Escalate interesting, complex and/or important cases to closed meeting
- Follow-up, collecting input, often via a survey
- Form a team to set-up and manage the survey, to process the results and present the outcome at a next closed meeting
- Finalization of the discussion. If deemed relevant for a broader community then:
 - Present at open meetings (EBF and/or other)
 - Publish in a scientific journal

Did we evolve?

- 2006
 - Nov - Inauguration of EBF: 12 member companies
- 2007
 - Jan - 1st Closed meeting: 16 member companies
- 2008
 - Jan - 24 member companies
 - Dec - 1st Open Meeting: 250 participants
 - Dec - Inauguration of EBF IGM: 14 member companies
- 2009
 - Jan - 26 member companies
 - Dec - IGM meeting: 16 member companies
 - Dec - 2nd Open Meeting: 400 participants
- 2010
 - Jan - 28 member companies
 - Apr - Register EBF as non profit
 - Aug - Design new EBF -> EBF 2.0
 - Sep - Members agree on new EBF 2.0

Yes !



“EBF v2.0”

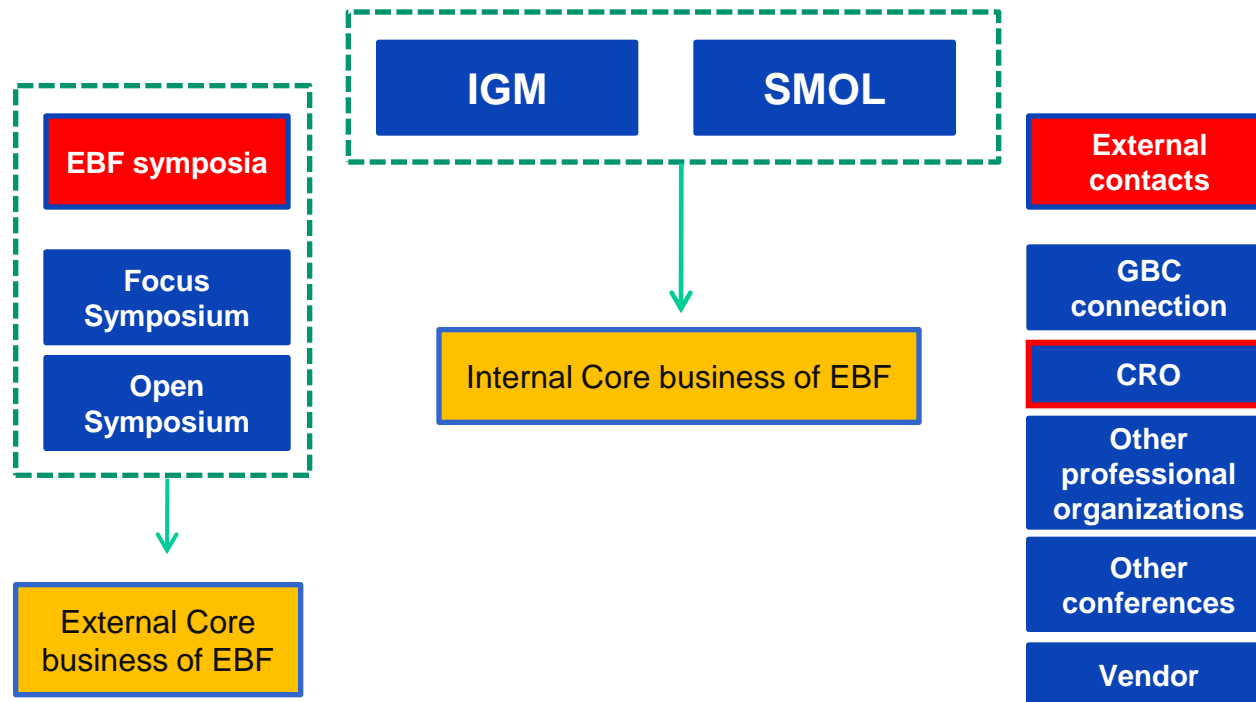
Highlights of EBF v2.0

- Merger of EBF and EBF IGM to form Strategy team
- Create format to manage global harmonization
- Ambition to create of a broader BA network in Europe
 - Opportunities for companies outside EBF core to join and/or participate as associated members
 - o Possibility to form sub-consortia on science and process
 - o Level of partnership: scientific partners (as per charter) and co-authorship in publications/recommendations
 - Opportunities for young scientists to develop and work in external environment
- Contribute to scientific discussion
- Increase impact through recommendations, publications, and participation at international meetings
- Consolidation of original values as mentioned in charter and translated in ground rules

Board (as per charter)

Steering Committee

Strategy Meeting team
(SMT = SC, IGM, SMOL)

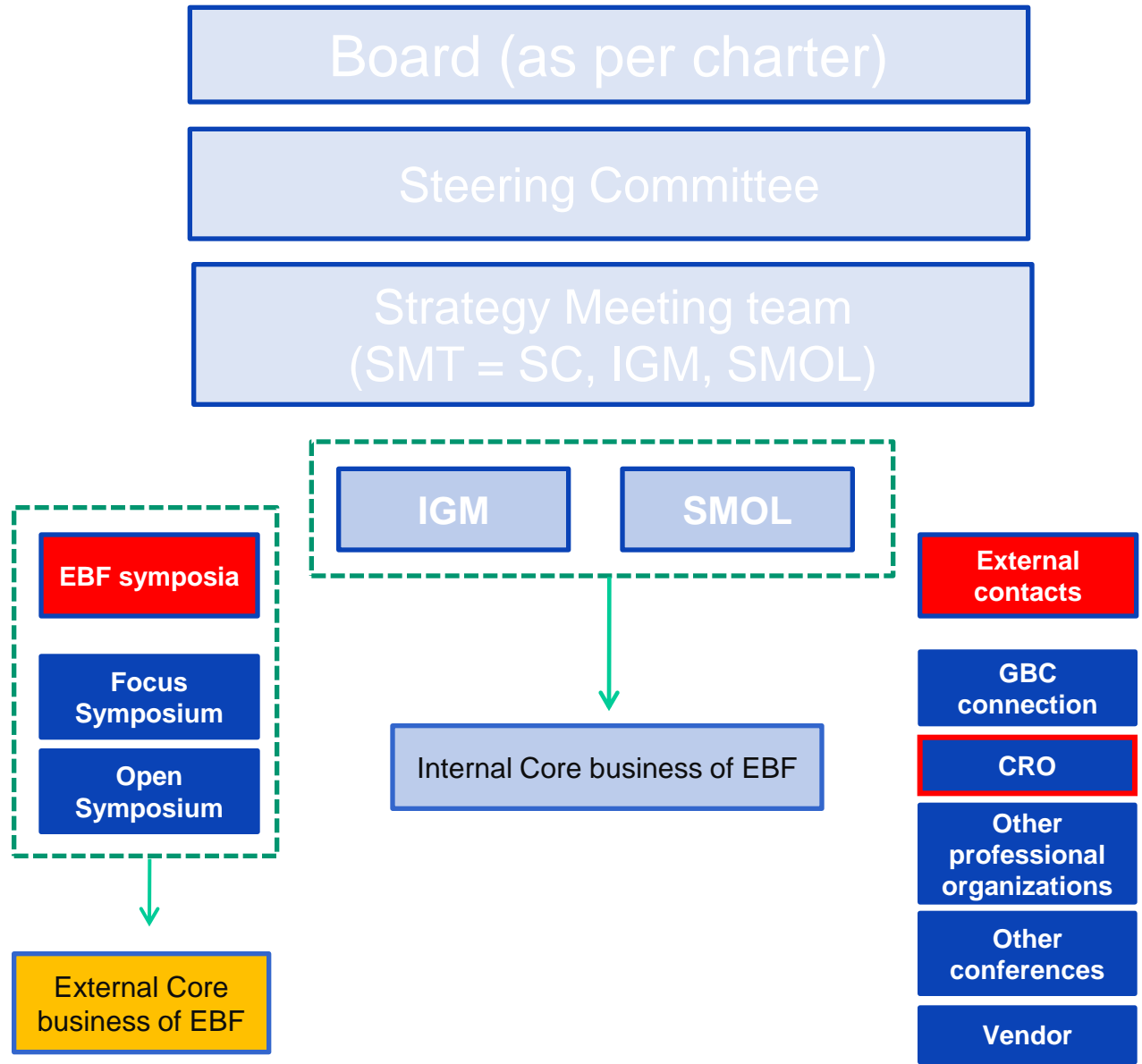


Operating Structure

- **Board = legal entity**
 - As per charter of non profit
 - 5 members, all members of EBF
 - Responsibilities described in official charter

- **Steering Committee (SC)**
 - Merged EBF and EBF-IGM Steering Committee
 - Philip, Berthold, Silke, Michaela, Peter, Margarete

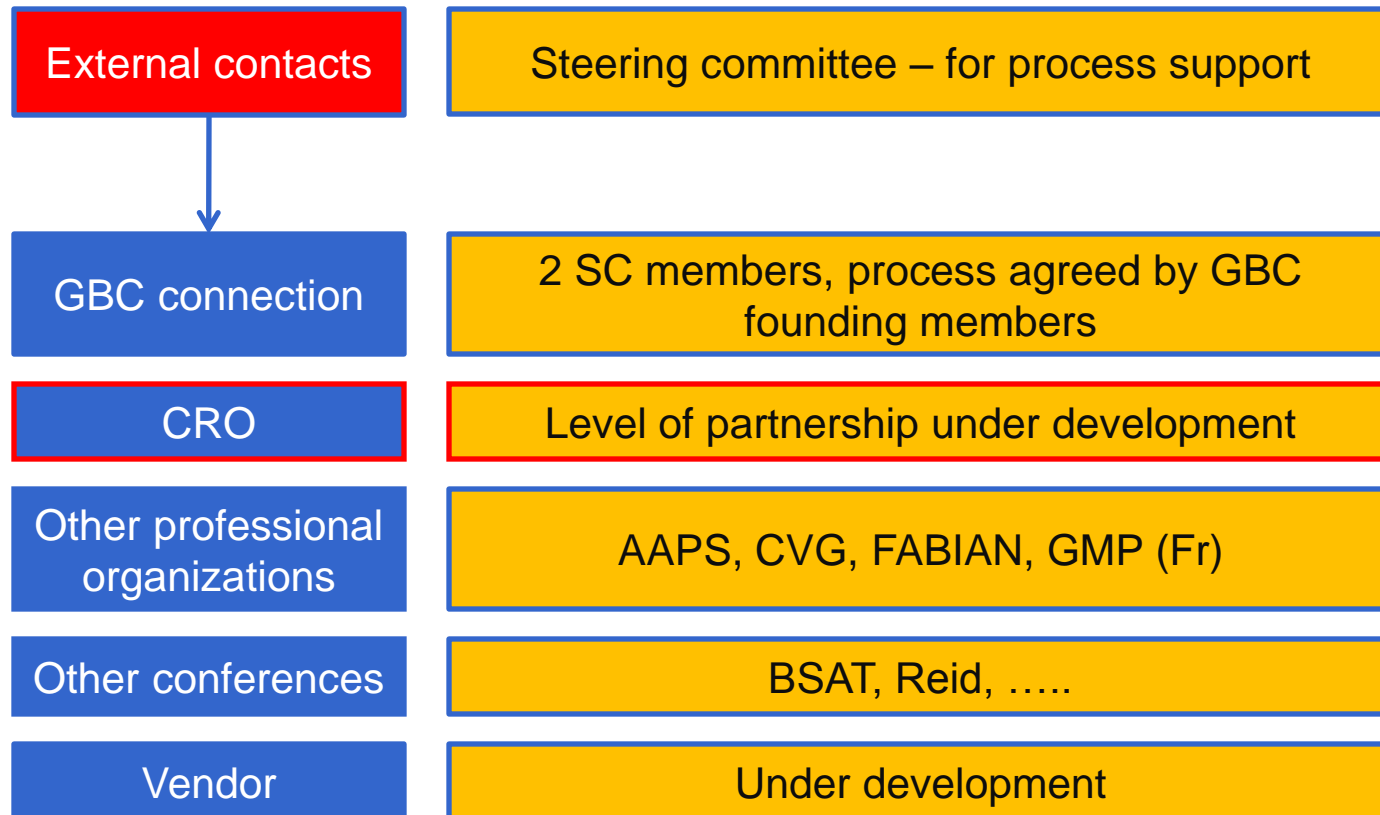
- **Strategy Meeting Team (SMT)**
 - All current EBF (= SMOL) members
 - All current IGM (= IGM) team members
 - EBF SC



Symposia



External contacts



- EBF-CRO consortium may contribute to
 - Surveys, e.g. WBS, DBS, Anomalous Results, Quality
 - Draft Guidelines
 - Technology platforms
 - LIMS Systems
 - ELN
 - Assay platforms
 - Better understanding and interpretation health inspectors' observations
 - sharing of experience from RA inspections (being mindful of confidentiality)
 - Jointly propose the standards (e.g. through GBC)

Ground rules for EBF / CRO Coalition Group (EBF-CRO-Group), cntd

- Labs need to have BA operation in Europe with a major focus on regulated Bioanalysis.
- CRO delegates assigned to potential EBF sub-consortia need to represent science and not business development
 - The representative is the single contact point.
 - Member should have (senior) experience in topic
 - Continuity of membership is stimulated (=no one time participation)