European Bioanalysis Forum

2011 Accomplishments
2012 Plans

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On behalf of EBF Steering Committee

4th EBF Open Symposium

16-18 November 2011
Barcelona, Spain

Mission

Our mission is to share, discuss, optimize and seek alignment on a broad array of bioanalytical topics including science, procedures, business tools and technology, and regulatory issues.

Internal discussions within EBF aim to recommend or influence opinions/procedures towards our members, business partners, regulatory bodies and any other stakeholders.

Going forward, EBF is providing guidance and recommendations on above topics to the European and Global bioanalytical community.

Commitment

A regional step stone for talented scientist and (emerging) leaders to engage in global discussion

A regional hub to bring feedback from other international organizations and meeting to EU

2011

A busy year

1. CRO integration

CRO integration

- Align with EBF mission
- Align with EBF ground rules
  - Needed updating to allow integration
- Align with legal charter
  - Needed updating to allow integration
- Align with IP management
  - Bioanalytical IP Pharma IP CRO

New Ground rules agreed in Strategy Meeting, March 2011

R&D based companies (Pharma & CRO) can become member:

- Members should be active in regulated bioanalysis in Europe (either hands on or managing from within EU).
- Members should contribute to EBF mission, by active participation to EBF meetings and/or in topic teams and/or in symposium organization)
- Each company can assign one representative for “Small” (SMOL) and one for “Large” (IGM) to the annual strategy meeting.
- A company can assign additional members to topic teams (TT), provided EBF SC sponsor and TT lead agree.

Ground rules, cntd

Expectations EBF representatives:

- The representative is the single point of contact for his/her area and represents EBF matters in their company (create awareness, get input, provide feedback).
- Attendance to strategy meetings is mandatory for representative (a replacement steps in when he/she cannot attend)
- Failure to actively participate for 1 (one) full year (i.e. absence from strategy meetings, active participation in teams) suspends membership for 1 year. Members will be notified by steering committee via e-mail.
- Member should have senior empowerment in own company on BA matters to facilitate active contribution to EBF discussion and follow up on actions decided at strategy or topic team meetings.

Ground rules (cntd)

- We don't :
  - Exchange portfolio or IP information
  - Allow advertisements of members or invites
  - Engage in business development
  - Misuse the EBF brand and logo
    - ✓ Any public use of the brand and logo should be approved by the SC
- EBF only represents EBF and not individual member companies
- EBF members presenting on behalf of EBF, represent EBF's agreed vision and refrain from promoting their personal or their company's vision.
- All external presentations should be approved by the SC for final release.
- Engagement in single vendor relationships is strictly limited and needs approval by the SC
- EBF will not present at a 'purely for profit' meeting

CRO integration

- Align with EBF mission
- Align with EBF ground rules
  - Needed updating to allow integration
- Align with legal charter
  - Needed updating to allow integration
- Align with IP management
  - Bioanalytical IP Pharma =/ IP CRO
- In practice
  - Preparations started 10-2010
  - Integration agreed at 03-2011 Strategy meeting
  - First CRO enrolled 05-2011
  - Currently 15 CROs enrolled

2. From ‘Closed’ to ‘Strategy’ Meetings

From ‘Closed’ to ‘Strategy’ Meetings

Strategy meeting/year (Brussels Area)

- March timeframe
- Annual meeting of all EBF representatives from members.
- Agenda: define strategy of topics EBF wants to work on – i.e. topic teams
- Identify topic team leads and desired deliverables (and accompanying timelines)

Topics and Topic Teams - 1

EBF community joins at yearly strategy meeting to identify or confirm topics will (continue to) work on in that year.

Selection of a topic will result in a Topic Team (TT) taking this topic to its deliverable

At Strategy Meeting, EBF decides on scope and deliverable, and TT-leads are selected by EBF depending on scope

Each TT will have a minimum of 1 SC sponsor (which provides guidance in process)

Identification of Topics and Topic Teams - 1

At the Strategic Meeting

- Topics to be worked on in that year will be identified or continued
- Selection of a topic will result in a Topic Team (TT) taking this topic to its deliverable
- EBF community decides on scope and deliverable
- TT-leads are selected by EBF community depending on scope
- Each TT will have a minimum of 1 SC sponsor (who provides guidance in process)

Identification of Topics and Topic Teams - 2

- Topic team leads (TT-leads) – tasks
  - Composes TT
  - Manages progress (plan TCs, preparation of conclusion, resolution, recommendation, publication...
  - Shares draft conclusions with SC for input, consistancy and endorsment strategy prior to sharing broader
  - Shares conclusions for input, challenge and endorsement with EBF or EBF as appropriate
- TT leads connects regularly with SC sponsor for continuity/progress.
  - TT will be invited to SC TC at least once per Q
  - If budgets allows TT can meet once f-2-f funded by EBF
- TTactivities stop after deliverable.
- TT-Lead responsibility stop after deliverable

EBF Topic Teams 2011

TT-01: Whole Blood Stability
TT-02: Incurred Sample Stability
TT-03: influence of different counter ions of anticoagulant
TT-04: Tiered approach in validation
TT-05: Anomalous results
TT-06: Dried Blood Spots
TT-07: IS Response variability
TT-08: BA validation aspects of microdosing (incl. AMS)
TT-09: Alternative techniques to LC-MS
TT-10: Definition and handling of raw data
TT-11: CSV
TT-12: clinical Multi Center Trials
TT-13: GCP guideline
TT-14: Biomarker validation recommendation
TT-15: Effect of haemolysed / lipidemic / ”off target” matrices
TT-16: Formulation analysis
TT-17: Acyl-Glucuronides
TT-18 :Stability of Abs
TT-19 :Sense/nonsense of assessing Nabs
TT-20 :Challenge of free and total assays
TT-21 :Design of sample storage and logistics for LTS tests for proteins
TT-22 :Design of experiments
TT-23 :Selection of sample for ISR for LBA: a priori or after PK analysis?

3. Publications

- **EBF Conference Reports**

  Richard W Abbott, Ben Gordon, Peter van Amsterdam, Berthold Lausecker, Margarete Brudny-Kloeppel, John Smeraglia, Fernando Romero, Susanne Globig, Michaela Golob, Magnus Knutsson, Christian Herling, Eva Vieser, Philip Timmerman
  Conference Report 3rd Open EBF Symposium: From challenges to solutions
  Bioanalysis, April 2011, Vol. 3, No. 8, Pages 833-838

  Richard Abbott, John Smeraglia, Stephen White, Silke Luedtke, Leonarda Brunet, Elizabeth Thomas, Suzanne Globig, Philip Timmerman
  Conference Report EBF 1st Focus Meeting: Connecting strategies on dried blood spots
  Bioanalysis, Nov 2010, Vol. 2, No. 11, Pages 1809-1816

Publications cntd

- **Regulations**

  Henning Blume, Erich Brendel, Margarete Brudny-Klöppel, Sylvia Grebe, Berthold Lausecker, Gabriele Rohde, Christoph Siethoff
  Workshop/Conference Report on EMA Draft Guideline on Validation of Bioanalytical Methods
  European J. of Pharmaceutical Sciences 42(2011) 300-305

- **Blood Stability**

  Achim Freisleben, Margarete Brudny-Klöppel, Hans Mulder, Ronald de Vries, Marcel de Zwart, Philip Timmerman
  Blood stability testing: European Bioanalysis Forum view on current challenges for regulated bioanalysis
  Bioanalysis, Jun 2011, Vol. 3, No. 12, Pages 1333-1336

Publications cntd

- **Anti-coagulant counter ion**

- **Editorial**
  Carl Johan Sennbro, Magnus Knutsson, Philip Timmerman, Peter van Amsterdam
  Anticoagulant counter ion impact on bioanalytical LC–MS/MS assay performance: additional validation required?
  Bioanalysis, November 2011, Vol. 3, No. 21, Pages 2389-2391.

- **Research Articles**
  Carl Johan Sennbro, Magnus Knutsson, Peter van Amsterdam, Philip Timmerman
  Anticoagulant counter ion impact on bioanalytical LC–MS/MS assays: results from discussions and experiments within the European Bioanalysis Forum
  Bioanalysis, November 2011, Vol. 3, No. 21, Pages 2393-2399

Publications cntd

- **DBS - Dried Blood Spots**

Philip Timmerman, Steve White, Susanne Globig, Silke Lüdtke, Leonarda Brunet, Christopher Smith, John Smeraglia
EBF and dried blood spots: from recommendations to potential resolution
Bioanalysis, Aug 2011, Vol. 3, No. 16, Pages 1787-1789.

Philip Timmerman, Steve White, Susanne Globig, Silke Lüdtke, Leonarda Brunet, John Smeraglia
EBF recommendation on the validation of bioanalytical methods for dried blood spots
Bioanalysis, Jul 2011, Vol. 3, No. 14, Pages 1567-1575.

Richard Abbott, John Smeraglia, Stephen White, Silke Luedtke, Leonarda Brunet, Elizabeth Thomas, Suzanne Globig, Philip Timmerman
Conference Report EBF 1st Focus Meeting: Connecting strategies on dried blood spots
Bioanalysis, Nov 2010, Vol. 2, No. 11, Pages 1809-1816

4. Successful meetings

- 3rd EBF Open symposium 2010
  - almost 400 delegates

- 2nd Focus Meeting – new goal of EBF
  - Large meets small
  - Almost 200 delegates
  - Well received scientific program
  - No strikes, no volcano, no snow storms

- EBF DBS workshop
  - Resulting in EBF DBS consortium

5. Contributions to other meetings

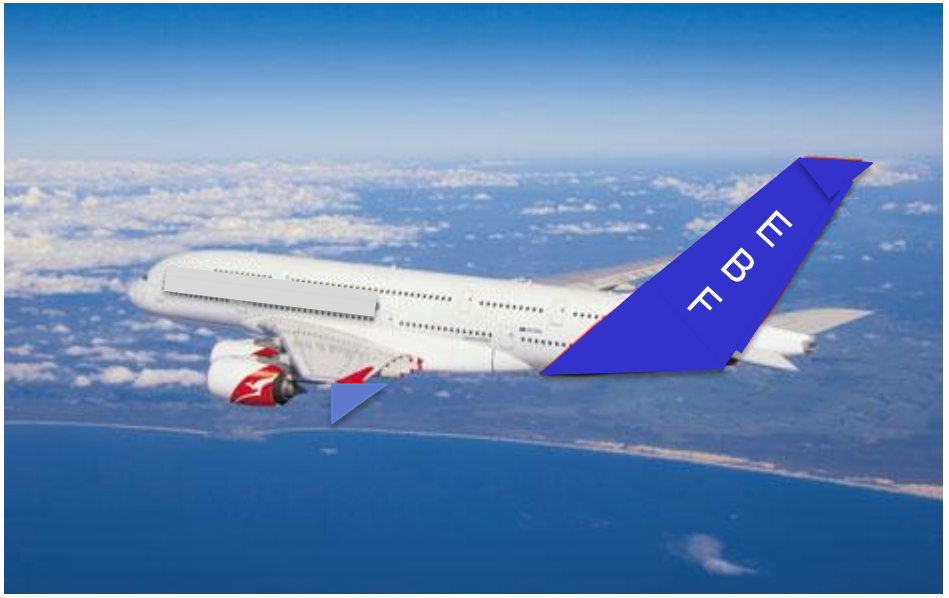
- National Biotechnology Conference
  - Symposium on:
    Update on Global Harmonization of Bioanalytical Regulations, Global Bioanalytical Consortium (GBC) and Impact on Ligand Binding Assays
  - 4 presentations and panel discussion

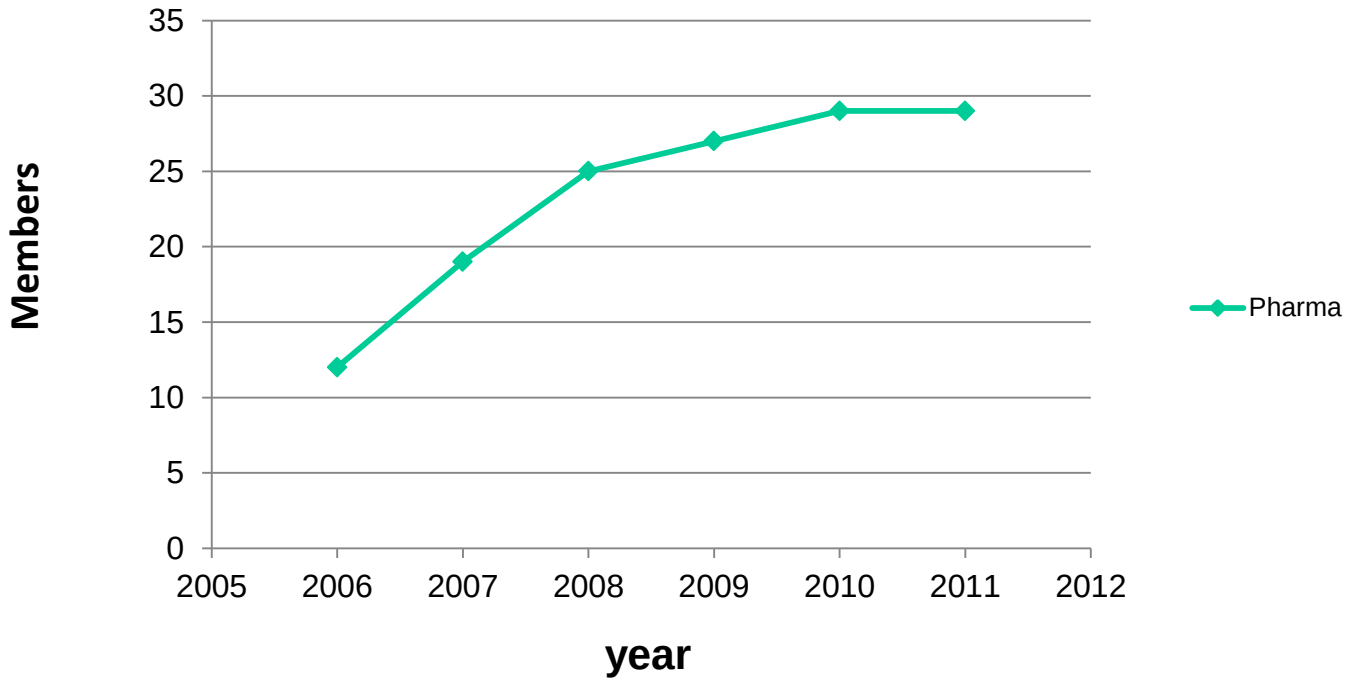
- Reid Forum
  - Presentation on Anti-coagulant counter ions
  - Presentation on DBS

2012

A challenging year

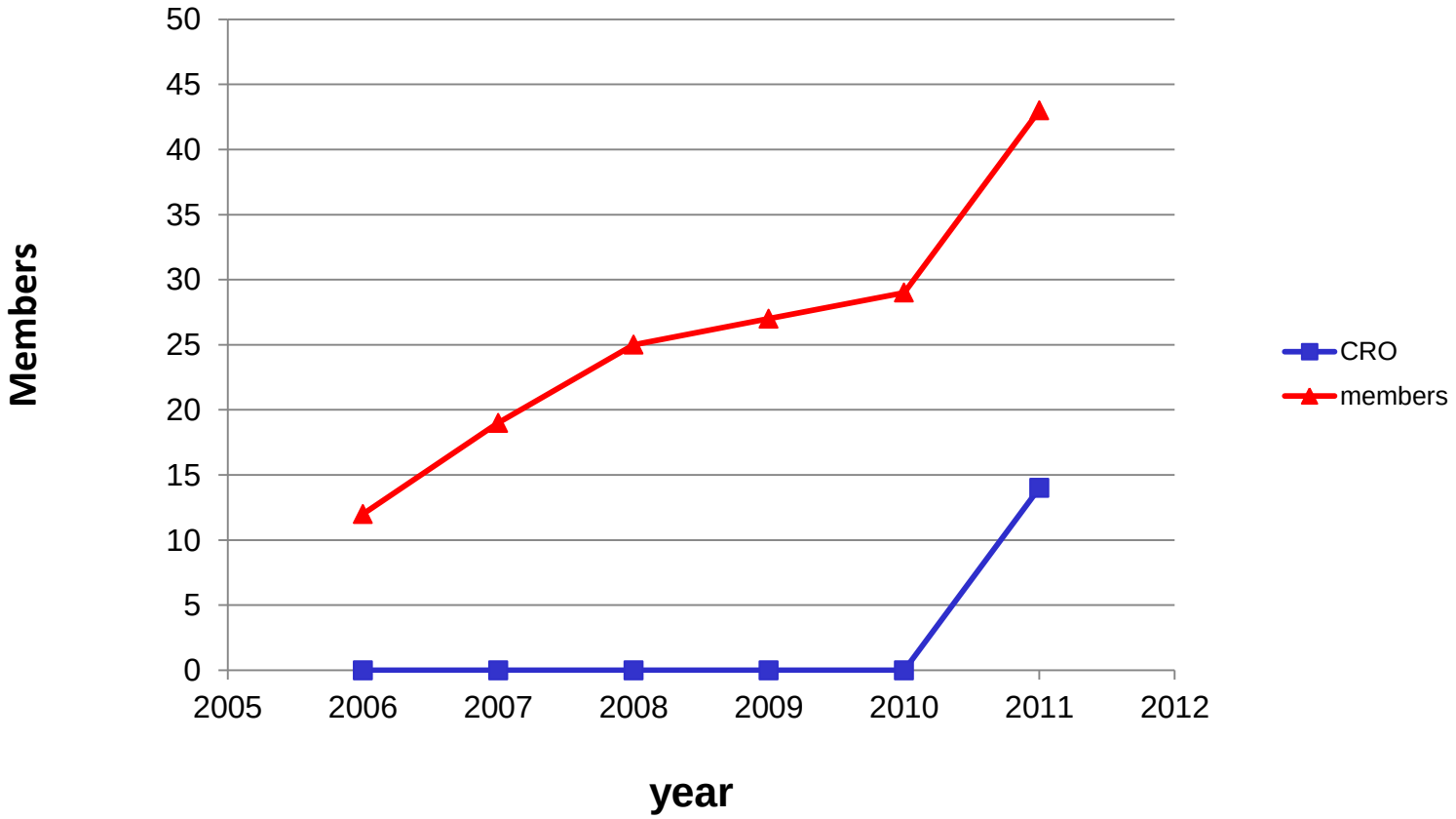
Q1-2011: membership cruising altitude





From Q2-2011 onwards:

new take off



Challenges

- It took EBF 1-2 years to build the trust and confidence with a group of 25-35 people - 2006-2007
- 2011:
  - Currently 20-25 new faces joining from CRO
  - At the same time, due to re-orgs in Pharma, also 5-10 new faces from Pharma are joining

- Approximately 30 new faces, less familiar with EBF dynamics and executions of ground rules
  - EBF will need some time to regain cruising altitude
  - Next strategy meeting will be very important
  - EBF determined to maintain on course wrt content and impact

2012 - plans

- Continue CRO integration
  - Remain on track with Mission
  - Recognize challenge
- Optimize Strategy meetings
  - Size doubled !!
  - Multilayered interest: SMOL - IGM
- Further capitalize on Publications strategy
  - As currently planned by topic teams
  - As will be agreed in Strategy Meeting
- Symposia & workshops
  - 3rd Focus Meeting 12-13 June, Brussels
  - 5th Open Symposium, 14-16 November, Barcelona
  - Workshops will be defined though out the year, as needed

Strategy Meeting 2012

- Internal to EBF members
  - Currently 67 individuals are invited
- Where: Limelette, Brussels area, 13-15 March
- Agenda
  - Make time to get to know each other
  - Define 2012 strategic topics (→ Topic teams)
    - Evaluate 2011 Topic team dynamics – what worked?
    - Evaluate Topic team to be continued/discontinued
    - Identify new topics to work on
- ✚ internal workshop on EMA-BMV 15-16 March
  - "How did we implement the EMA guideline within EBF?"
  - Goal: ensure harmonized interpretation and implementation of EMA guideline by all EBF members

EBF organized Symposia 2012

- 3rd Focus Meeting, 12-13 June, Brussels
  - 1.5 days: Emerging Technologies and their Applications in the Regulated Bioanalysis Laboratory
  - 0.5 days: GBC input and feedback, again inviting 4-6 GBC HTs to engage with us
- 5th Open Symposium, 14-16 November, Barcelona
  - For sure even more stimulating compared to 2011