Updates from the Global Bioanalysis Consortium

presented at the 4th EBF Open Symposium
Barcelona, 16NOV2011
Scope

Slides and presentation aim at providing a very short update with focus on this week’s meeting and most important GBC activities

More info on

http://www.globalbioanalysisconsortium.org/
<table>
<thead>
<tr>
<th>Region</th>
<th>Members</th>
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</table>
| North America (US + Canada) | Mark Arnold (AAPS)  
                        Binodh DeSilva (AAPS)  
                        Fabio Garofolo (CVG) |
| Latin America (South America + Mexico) | Rafael Barrientos (AcBio) |
| Asia Pacific (Asia + Pacific area)      | Shinobu Kudoh (JBF)  
                        Shrinivas Savale (APA-India)  
                        Daniel Tang (SBDG&BBDG) |
| Europe (Europe + Africa/Middle East)    | Peter van Amsterdam (EBF)  
                        Michaela Golob (EBF)  
                        Philip Timmerman (EBF) |

Red = Present today
NEW insights developed at GBC-SC meetings

Desire for **increased engagement**, input and contribution from the different regions

- The current team dynamics and composition may not sufficiently engage current non contributors in the broader scientific community
- Open discussion

Desire to provide opportunity for **regular updates** on GBC progress in an open format

- The current process may lead to a significant period of ‘radio silence’
- Prevent that all GBC-proposals come as one avalanche at the global meeting, which may be too much to manage if not previewed
- Provide regulators a chance to get better understanding of activities of GBC
Proposal - How?

Shift **GBC Global Meeting** from Q2 to **Q3 2012**.

Use appropriate **2011-2012 regional meetings** in all 4 regions (best attended and most affordable in each region, >1x region) to give a flavor of the progress we are making.

- If the regional meeting can accommodate, include a **GBC session** in those meetings to provide update and allow input
- Invite **4-5 topic HT-L** (or a regional representative from those teams) to present the progress of their teams and to share.
- Stimulate HT-SC(s) to present **high level progress** on other topics, with input from other HT
- Engage with meeting organizers how to optimize **GBC visibility** during the meeting
- **Publish** outcome as a rapid communication to ensure all regions connect (GBC website or “Bioanalysis”)
- Inviting organizations to provide travel assistance
Potential win-win

• **Connect** GBC better with the regions
  - Reconnection with supporting organizations as our day to day supporters
  - All regions get expanded opportunity to be involved

• **Engage** and inform a broader scientific community in advance of the global meeting
  - Allow BA community to comment within the comfort zone of their region
  - Allow BA community to comment to their regional organizations

• Provide the opportunity to **publish** a summary of thinking in advance of the global meeting
  - Allow participants to know what’s coming
  - Be more engaged in the global meeting and not be caught by surprise

• Create visibility, recognition and connectivity in regions
  - for HT-L and HT members
  - for SC members

• Create flexibility to present on topics in need of **influencing current thinking** of regulators or on emerging guidelines
Proposed way forward

HT-L identification

HT identification

HT working on content working close with SLT

Global Meeting

3-day Conference in a EU city easy to reach for all in week of Sept. 24, 2012

SLT f-2-f Consolidation and joint discussion of all topics in preparation of 1st Global Meeting

Other regional meetings

identified regional meetings

- Invite 4-5 topics to present the progress of their teams and to share.
- Present high level progress on other topics and Get input

Start up phase

2011

2012

today
Proposed way forward – correction to AAPS

- **HT- L identification**
- **HT identification**
- **HT working on content working close with SLT**
- **SLT f-2-f**
  Consolidation and joint discussion of all topics in preparation of 1st Global Meeting
- **Global Meeting**
  3-day Conference in Rome (Italy) in week of Sept. 24, 2012
- **2011**
- **2012**
- **Today**

**Identified regional meetings**
- Invite 4-5 topics to present the progress of their teams and to share.
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Proposed way forward - communication

HT identification

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Global Meeting
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**Proposed way forward - communication**

**Final draft slides**
Consolidation of slides from all HTs in (mandatory) 2 day HT-L/SC F2F Meeting
Capitalize on travel to a US based BA conference of CVG San Antonio or NBC/ASMS in San Diego.

**Final Slides ready**
Publish on GBC website for global BA community to read, in preparation of Global Meeting

**Updated final slides ready**
Publish on website

**Global Meeting**

**Conference report(s)**
Publication strategy under discussion

**Approximate dates**
- March/May
- June/July
- September
- October
- Q1/Q2 2013

2012
In practice at EBF 4th Open Symposium

• 8-10 teams volunteered to give update on progress and get input, but we only had room for 4:
  – **A1: Scope and Regulations**
  – **A6: Stability**
  – **L6: Immunogenicity**
  – **S1: Small molecule specific run acceptance**

• In addition, session includes round table, moderated by SC members from all 4 regions

• Use the time at the meeting to connect to other GBC SC, HT-L or HT members

• Meet & Greet for GBC-SC, HTLs and HT-members on Thu 17 during lunch break (1:00 to 2:00 PM). in the Breakout Ballroom next to the sponsor booth area
Future meetings

Identified meetings qualifying for inclusion GBC session

- Fit with respect to timing (*italics*= post GBC meeting)
- Fit with respect to willingness of organizers to include GBC session
- Meetings potentially qualifying – further discussion with meeting organizers needed

**NA:**
- Mar. 2012: **6th WRIB** (CVG) – San Antonio, USA
- May 2012: **NBC** (AAPS) – San Diego, USA
- May 2012: **ASMS** – Vancouver, Canada
- Jul. 2012: **Land O’Lakes** – Wisconsin, USA
- Sep. 2012: **APA USA** (BSAT) – Boston, USA
- Other regional meetings (e.g., DVDMG)

**EU:**
- Nov. 2011: **4th EBF Open Symposium** – Barcelona, Spain
- Jun. 2012: **3rd EBF Focus meeting** – Brussels, Belgium
- Nov. 2012: **5th EBF Open Symposium** – Barcelona, Spain
- Other regional meetings (e.g., Fabian, French GLP,..)

**APAC:**
- Feb 2012: **APA India** (BSAT) – Ahmadabad, India
- Mar. 2012: **JBF**, Tokyo Japan
- Nov. 2012: **2nd APBC** (CVG) - Shanghai, China
- Other regional meetings

**LA:**
- May 2012 – **ACBio** – Sao Paulo, Brazil
- Other regional meetings
Acknowledgement

All scientists and experts working diligently in GBC

- HT members, HT-L, steering committee and founding members
- their respective managements giving support !!

All of you for your continued engagement in the months to come
Please hold questions to panel discussion