



Updates from the Global Bioanalysis Consortium

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



Global Bioanalysis Consortium
On harmonization of bioanalytical guidance

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/>



Global Bioanalysis Consortium

On harmonization of bioanalytical guidance

GBC-SC

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



Global Bioanalysis Consortium

On harmonization of bioanalytical guidance

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.

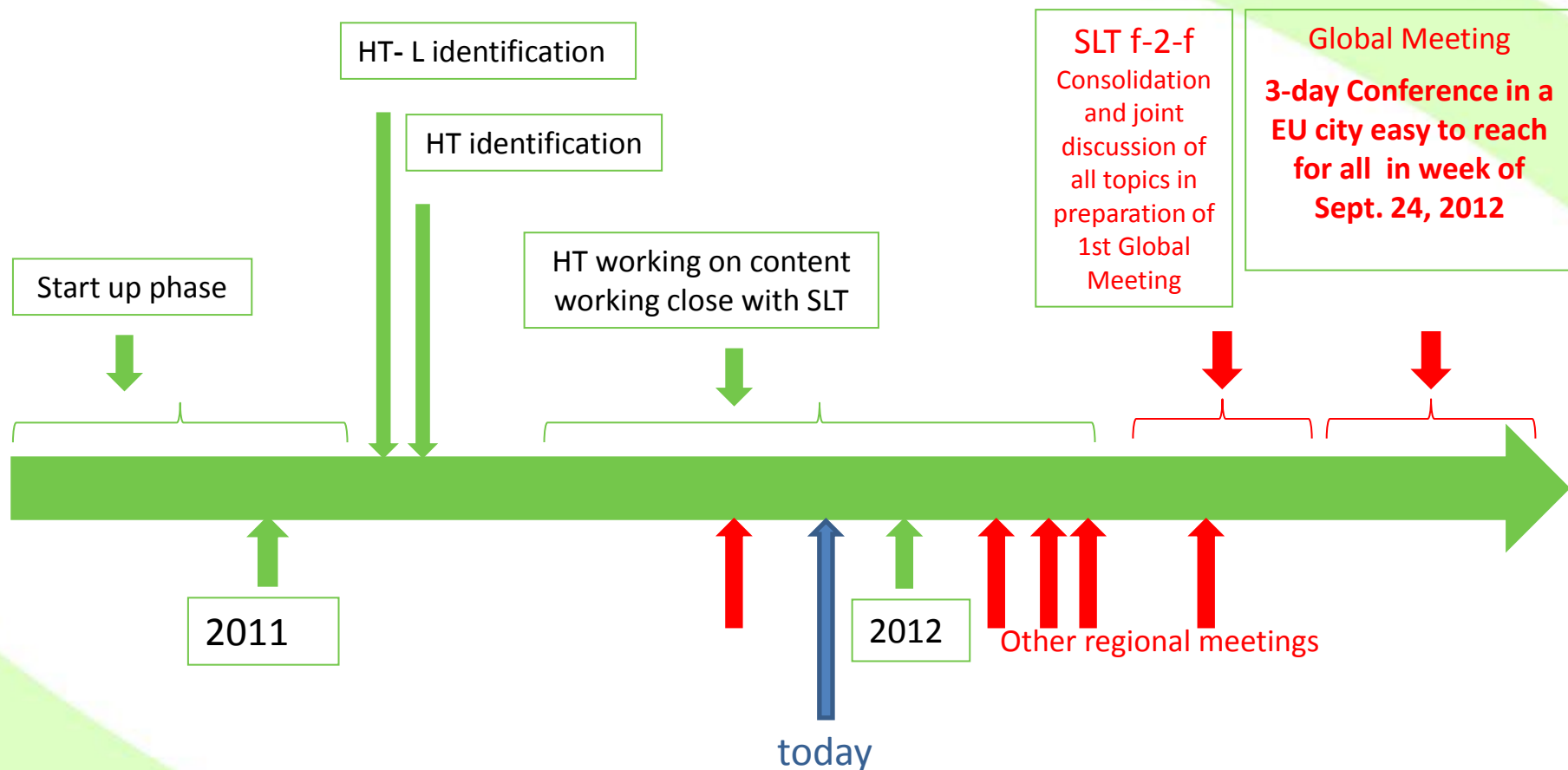
- If the regional meeting can accommodate, include a **GBC session** in those meetings to provide update and allow input
- Invite **4-5 topic HT-L** (or a regional representative from those teams) to present the progress of their teams and to share.
- Stimulate HT-SC(s) to present **high level progress** 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

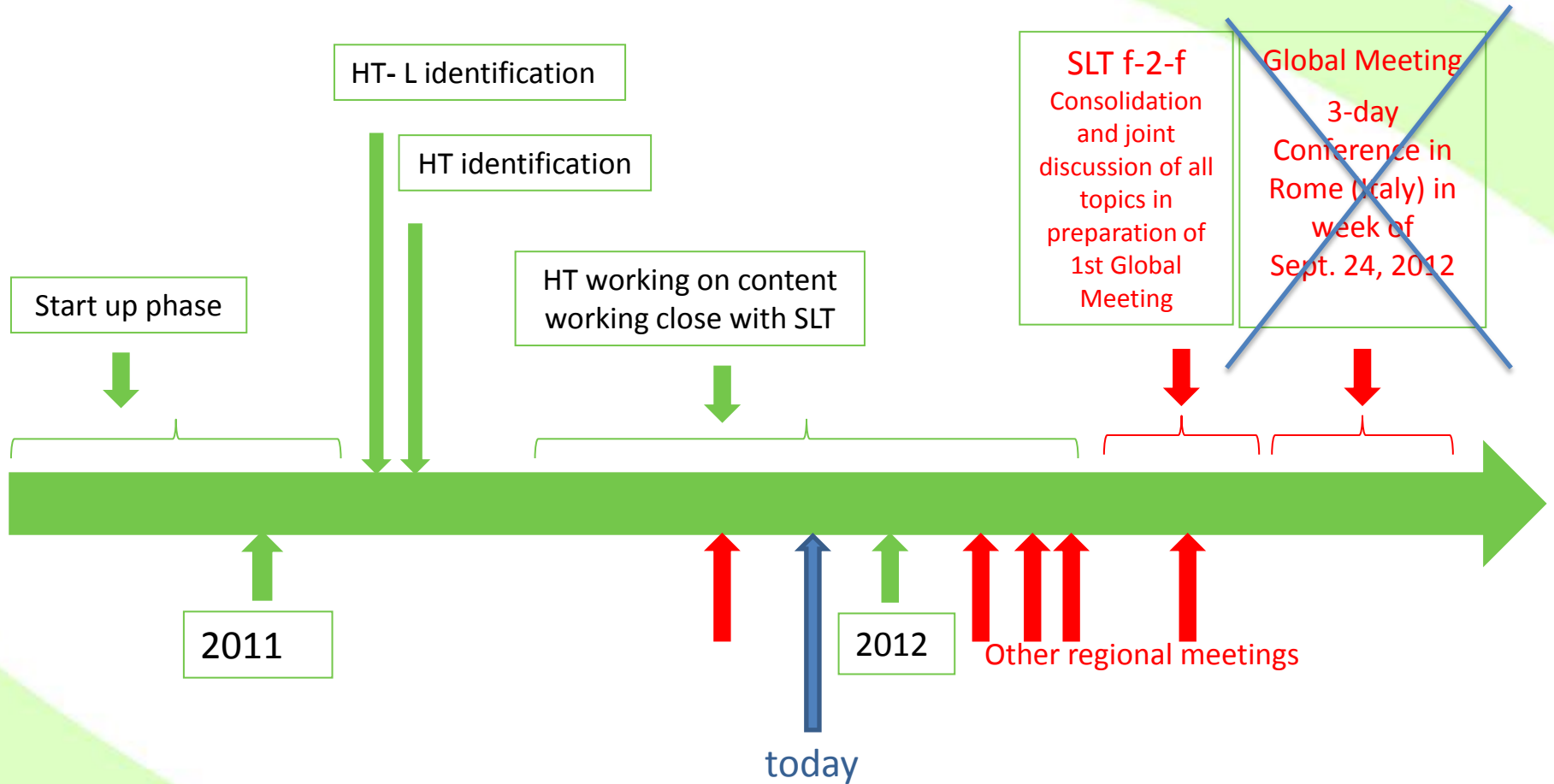


Identified regional meetings

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

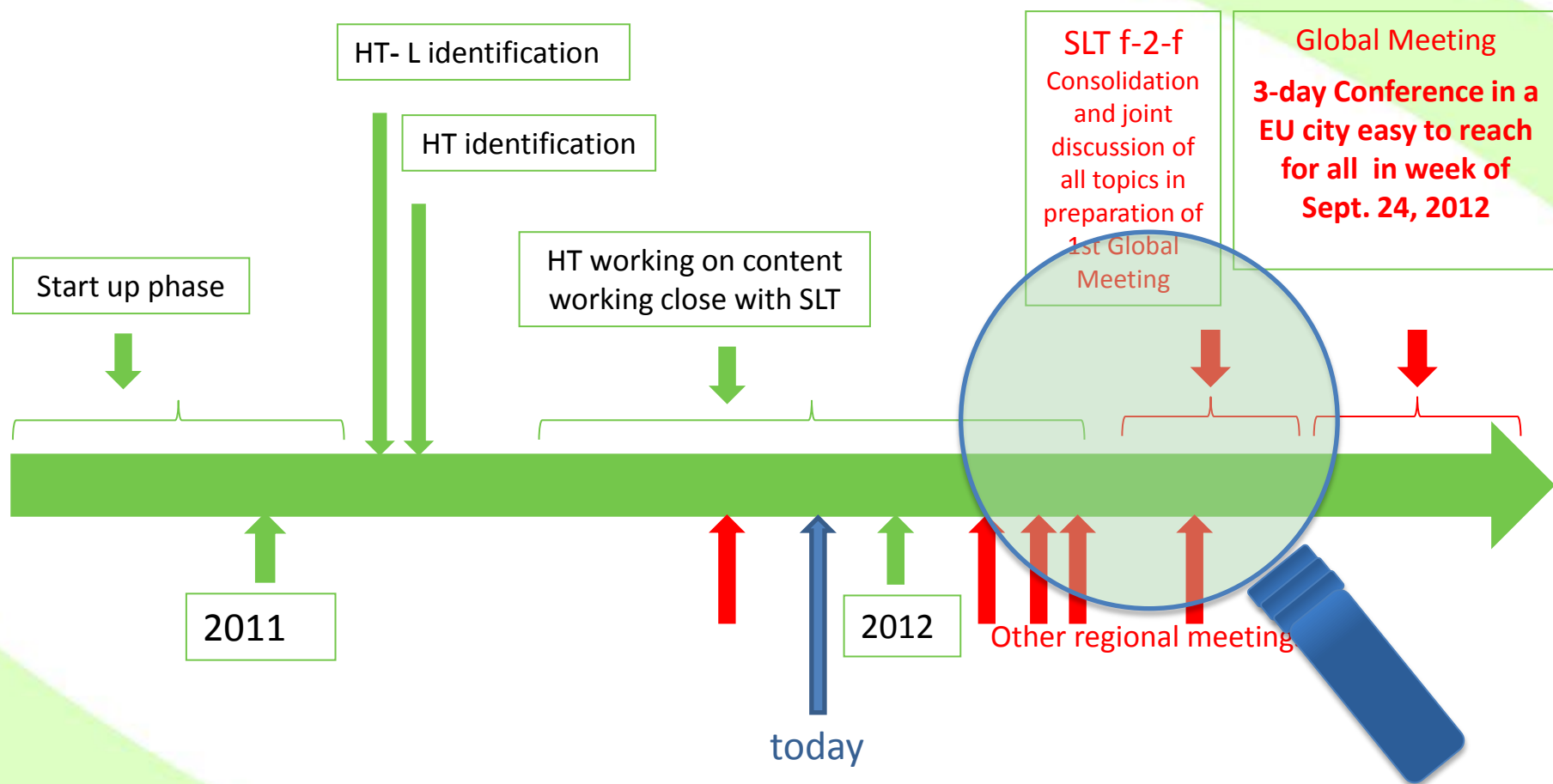


Proposed way forward – correction to AAPS



- 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

Proposed way forward - communication



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



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

Global Meeting

Updated final slides ready

Publish on website

Conference report(s)

Publication strategy under discussion

Approximate dates

March/May

June/July

September

October

Q1/Q2 2013

2012



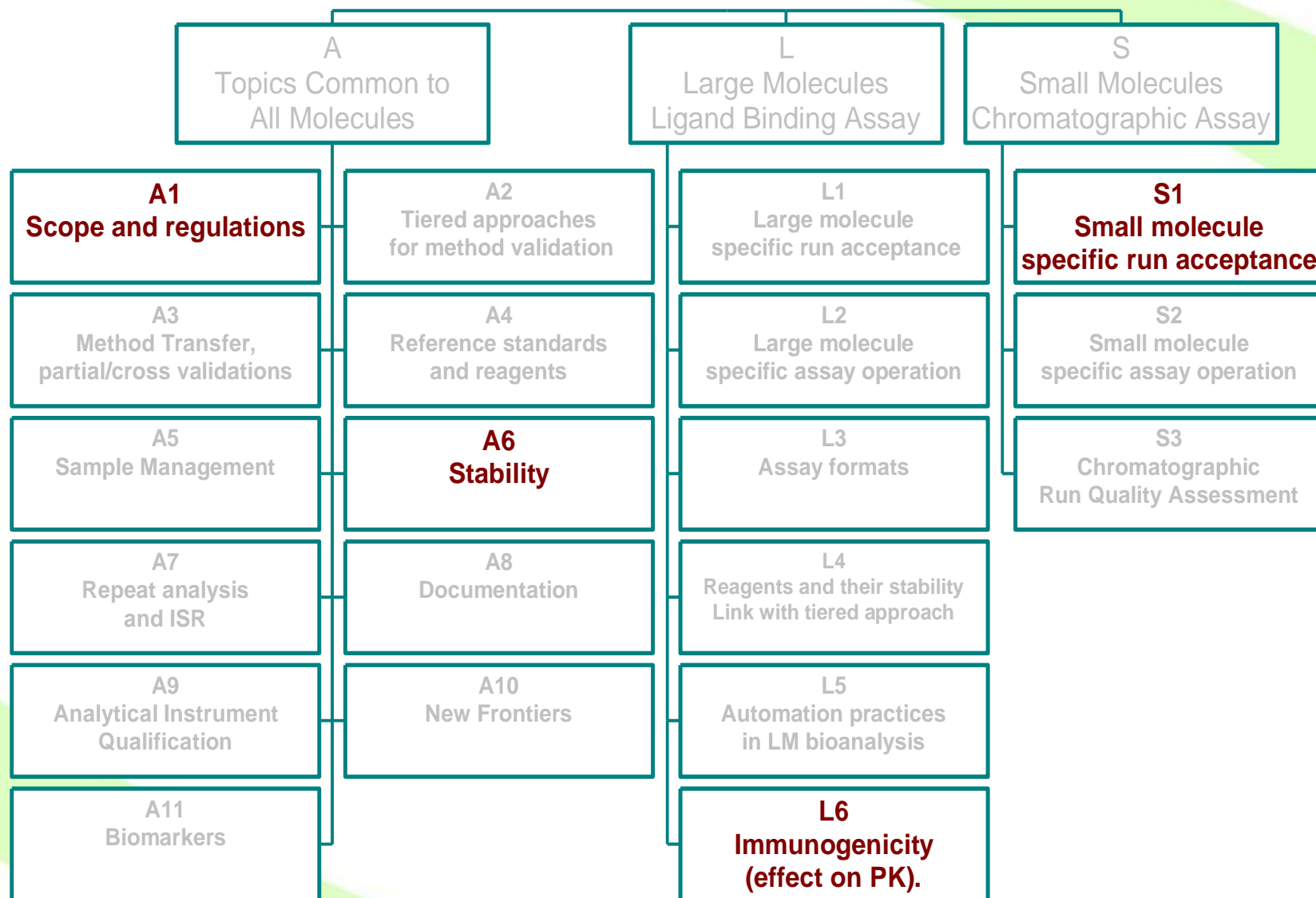
Global Bioanalysis Consortium

On harmonization of bioanalytical guidance

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

Harmonization Teams



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



Global Bioanalysis Consortium

On harmonization of bioanalytical guidance