



# Global Bioanalysis Consortium

## Important update: Change of venue and timing for Global GBC Meeting

Agreed @ HT-L/SC F-2-F in San Antonio (TX)  
30/31-MAR-2012



**Global Bioanalysis Consortium**  
On harmonization of bioanalytical guidance

# Summary

## Original planning

- HT-L/SC face to face in San Antonio
- Continue FB at regional meetings across all regions
- Load HT draft recommendation slides on GBC website in June
- GBC meeting in Noordwijk, the Netherlands 25-27 September
- Publish final recommendation slides on the website in October

## Updated planning

- HT-L/SC face to face in San Antonio (**done**)
- Load progress slides on GBC website from April onwards (**new**)
- Continue feedback and dialogue with broader scientific community at regional meetings across all regions (**intensify**)
- Load HT draft recommendation slides on GBC website in June
- ~~GBC meeting in Noordwijk, the Netherlands 25-27 Sept.~~ (**relocated – see next bullet**)
- GBC meeting moved to Washington DC area, 2 days prior to CC-V (**new**)
- ~~Publish final recommendation slides on the website in October~~ (**postpone until clarity on dates of GBC meeting**)

# What triggered this change?

FDA plan/communication to release draft of updated Guidance in summer. As follow up, AAPS/FDA will organize a 5<sup>th</sup> Crystal City meeting (CC-V) in Washington DC area within 90 days of draft Guidance release.

## Impact on GBC global meeting:

- CC-V and GBC global meeting involve the same audience separated potentially by only few weeks or months.
- Travel restrictions in industry will limit delegates to travel to two similar meetings in 2 different regions
- Attendance to CC-V may be prioritized by industry over GBC global meeting
- By connecting the GBC global meeting in time and place, GBC and delegates can participate in both meetings:
  - Provide consolidated feedback to and get input from the global community on draft GBC recommendations (= original intent of GBC global meeting)
  - At the CC-V meeting, share this consolidated GBC as input into the FDA draft Guidance (= impact as per GBC Mission & Vision)

# Additional reflections

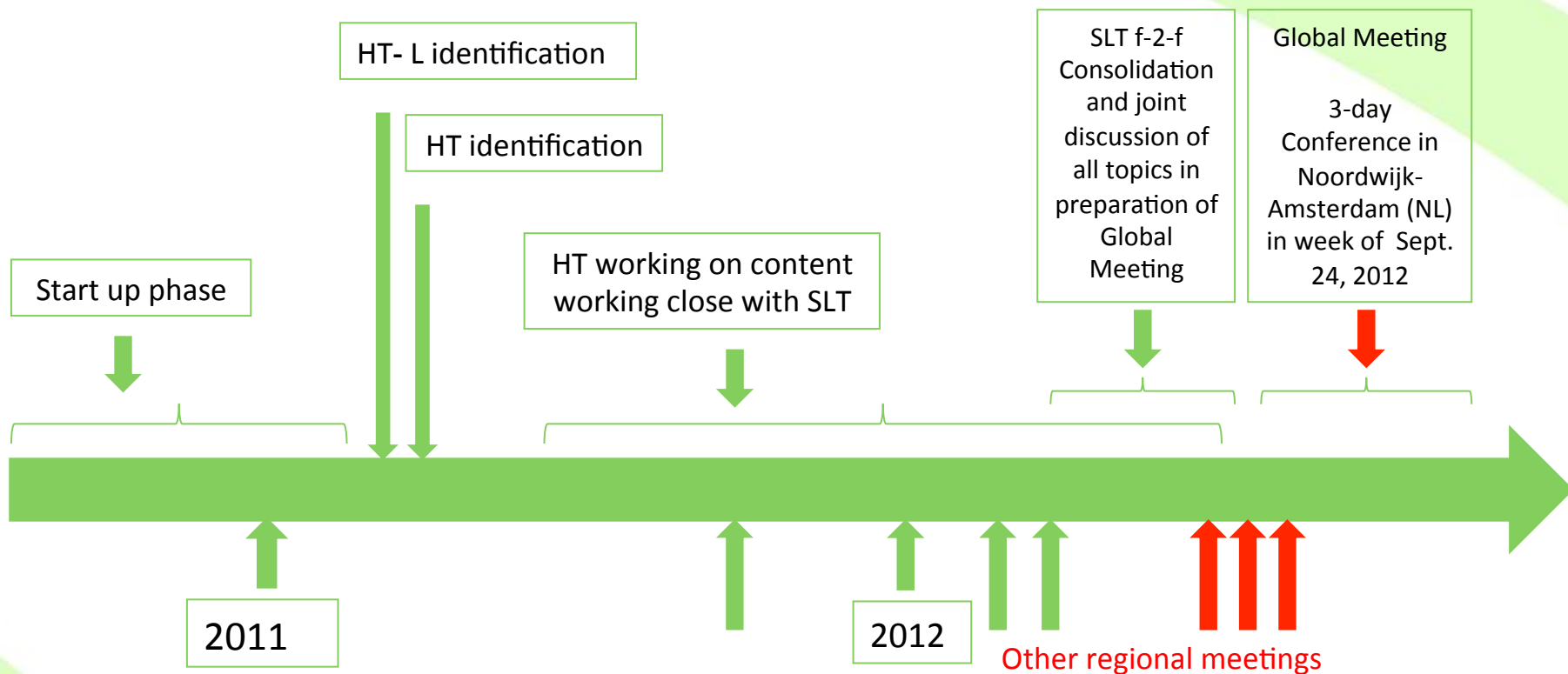
GBC needs to ensure their global mission is not redirected to only providing input on draft FDA Guidance but maintains its global perspective.

- Scope and agenda of GBC remains unchanged.
- Upon release of the draft FDA Guidance, Harmonization Teams(-L) needs to ensure that the scope and content of the team discussions doesn't change relative to the FDA guidance.
  - Nevertheless, major discussion points can be identified in preparation for discussion @ CC-V
- By intensifying the feedback from other regional meetings and earlier publication of our draft recommendation slides on the GBC website from April onwards, scientist in all regions should feel invited to also intensify their input.



# Original Proposed way forward

↓ : Done  
↓ : Planned



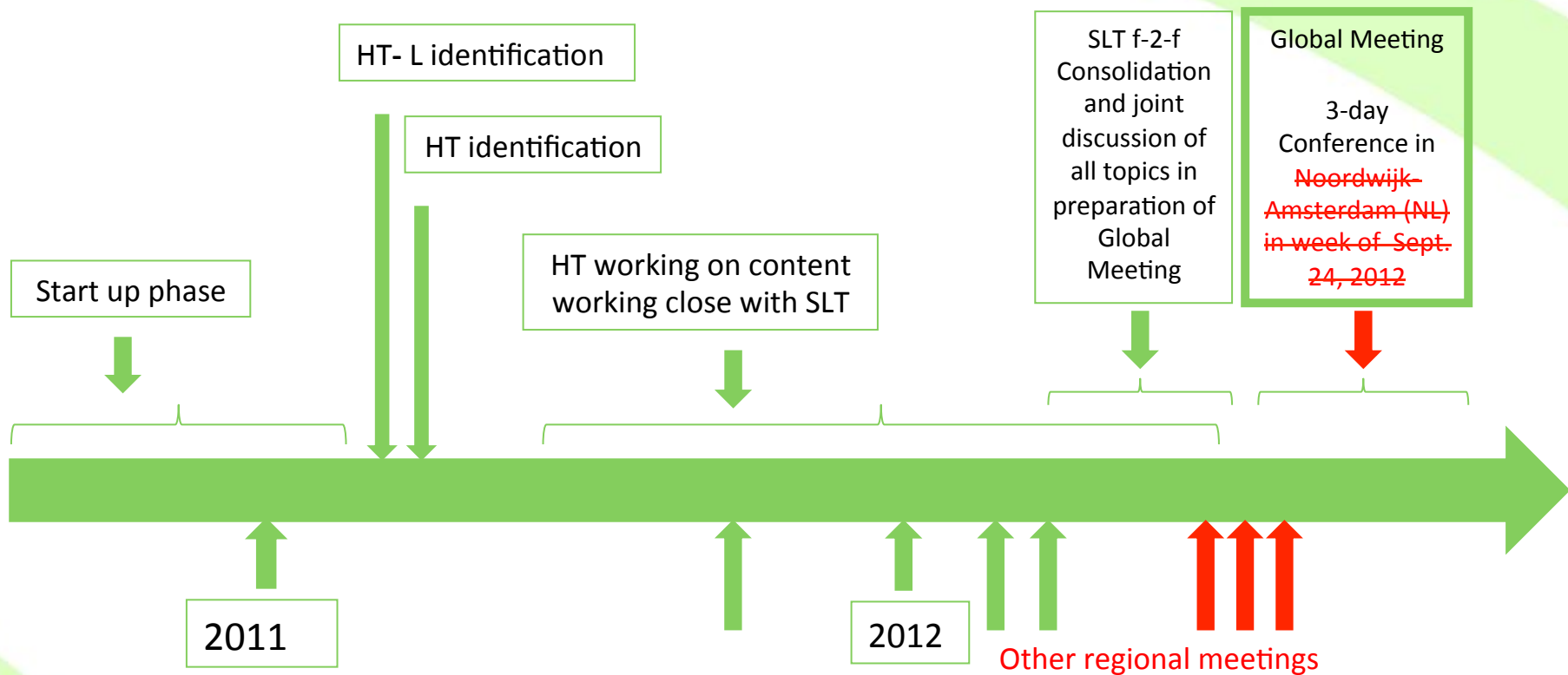
## Identified regional meetings

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



# Change

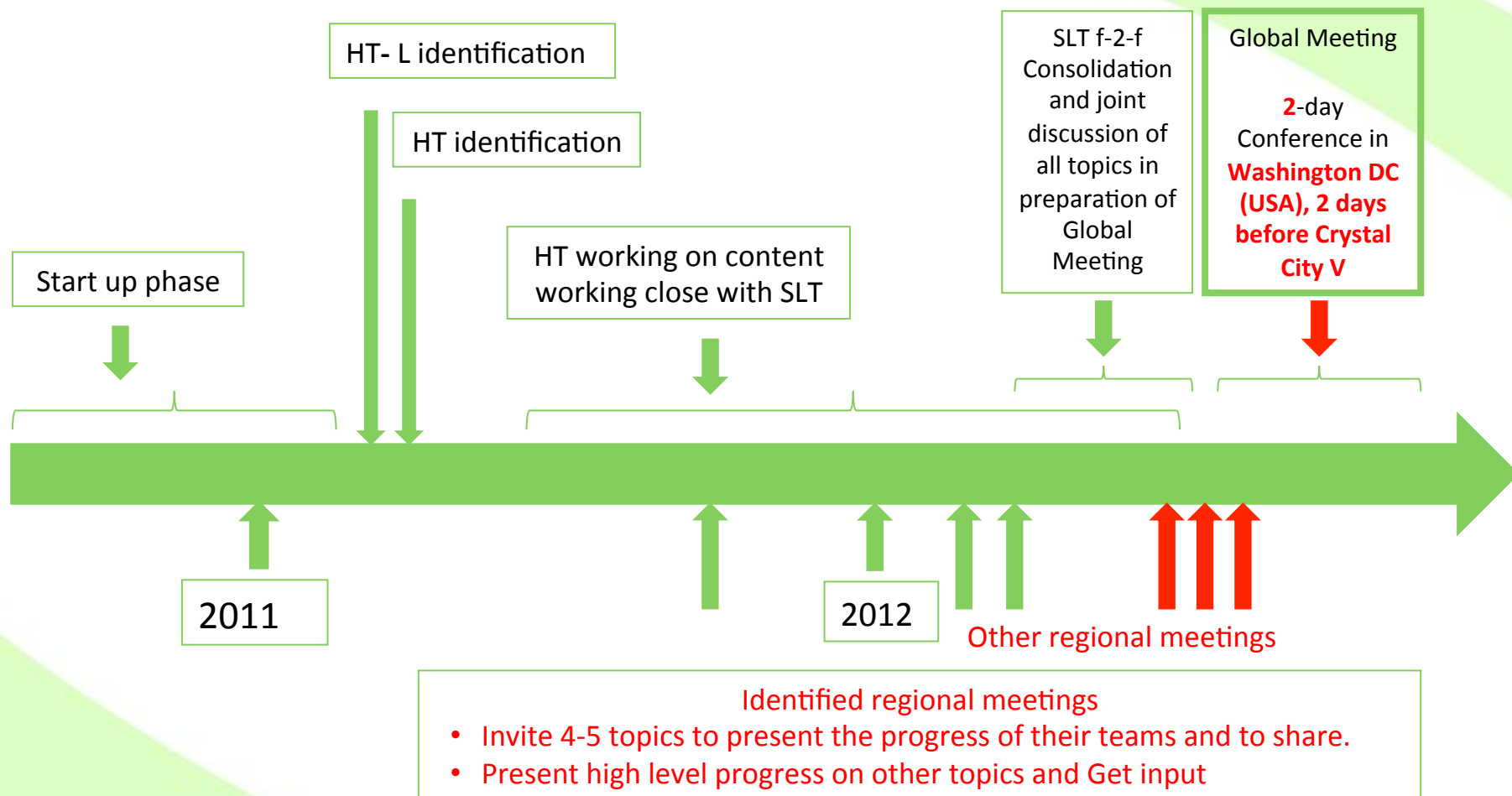
↓ : Done  
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- Identified regional meetings
- Invite 4-5 topics to present the progress of their teams and to share.
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# Updated Proposed way forward

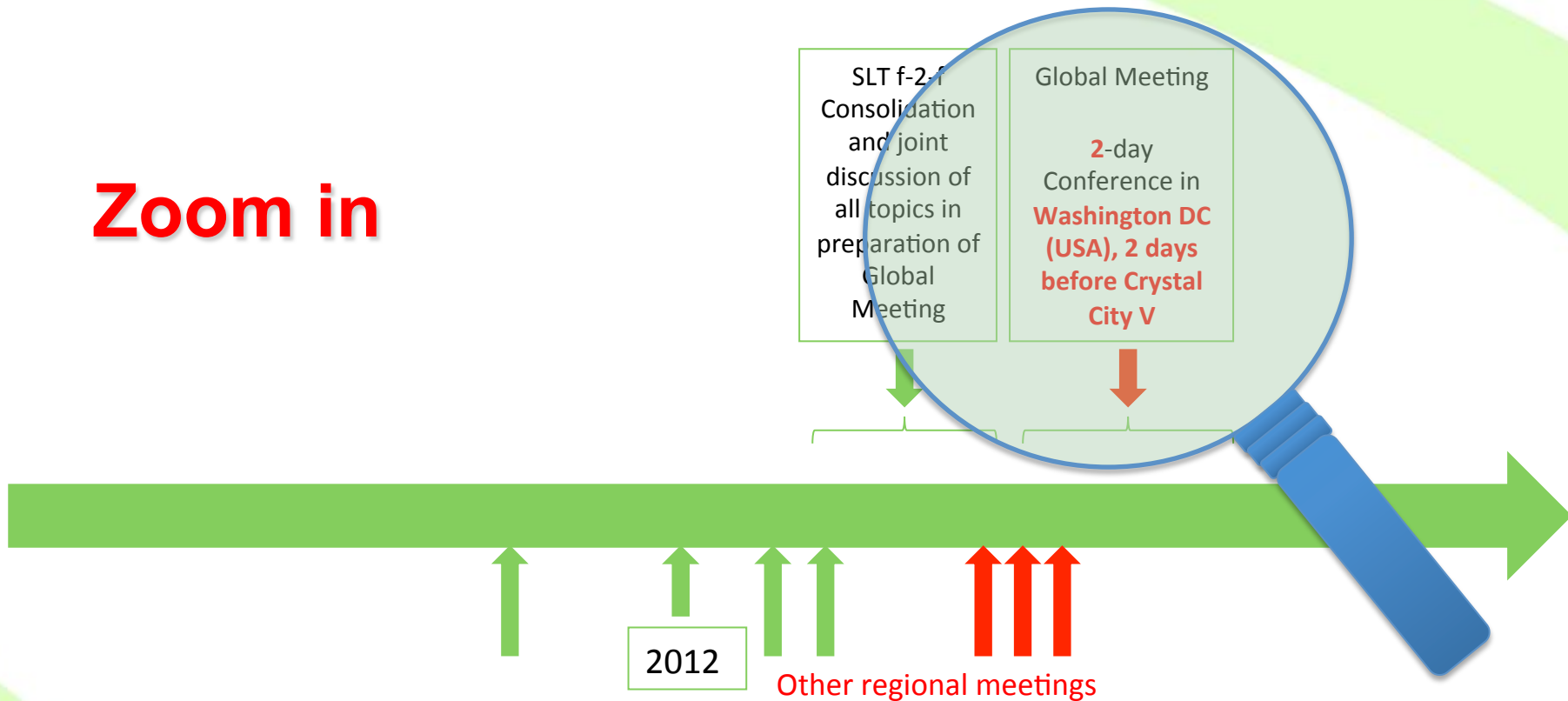
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# Updated Proposed way forward



↓ : Done  
↓ : Planned

## Zoom in





# Proposed way forward - details

 : Done  
 : Planned

Continued slide iterations, based on HT team meetings and input from the regions



**HT-L/SC F2F**  
San Antonio (Tx)  
\_Consolidation and joint discussion of all topics in preparation of Global Meeting

**draft slides**  
Consolidation of slides from all HTs from SA (Tx) on GBC website

**'Recommendation Slides'**  
on GBC website for all to read, in preparation of Global Meeting

**GBC Global Meeting**

2 days prior to CC-V

**Crystal City V**

max. 90 days after release of draft FDA Guidance.

March

April







e.o. June

exact date unknown today

2012



**Intensify** consolidation and consultation from teams and from regional meetings, building on slides presented at HT-L in San Antonio

-   
 APAC  
CPSA  
e.o.  
April
-   
 LA  
ACBio  
mid  
May
-   
 NA  
NBC  
mid  
May
-   
 EU  
EBF  
mid  
June
-   
 US  
LoL  
e.o.  
July
-   
 APAC  
JBF  
mid  
Aug.