

# Updates from EBF survey on unexpected results

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# EBF History – anomalous results

- Survey within EBF-IGM 2010
- Presentation at NBC May 2010
- Formation of EBF topic team 2010
- Two surveys within EBF 2010
- Anomalous result session at 2010 Barcelona meeting
  - Two presentations by EBF, survey results + case studies

# Summary from 2010 survey presentation

## Within EBF

- It is acknowledged that there is a certain probability that some samples won't meet the acceptance criteria/confirm the initial result, and that this does not jeopardize the validity of the data
- There is a common understanding that valid batches should not be rejected
- A lot of results are already checked – some call this check simply repetition, others call it formal investigation
- Respective measures are documented at least in raw data but often in the raw data and the bioanalytical report so that traceability is given
- Good scientific practice established within EBF member companies - know-how and scientific expertise of bioanalyst can not be replaced by SOPs/CAPA documents

# Activities 2011

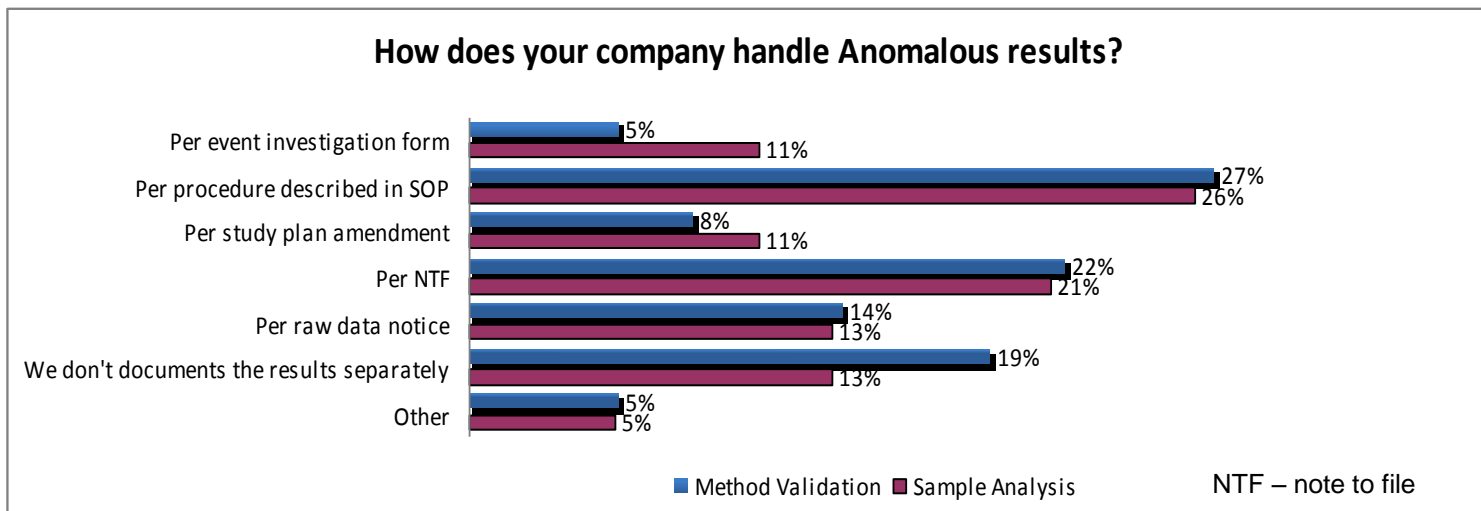
- Have EBF companies changed/adopted their view of anomalous results?
  - Discussion on last year's session
  - Regulatory inspections
  - Comments on submitted files
  
- New high level anomalous result survey, summer 2011

# Survey anomalous results - 2011

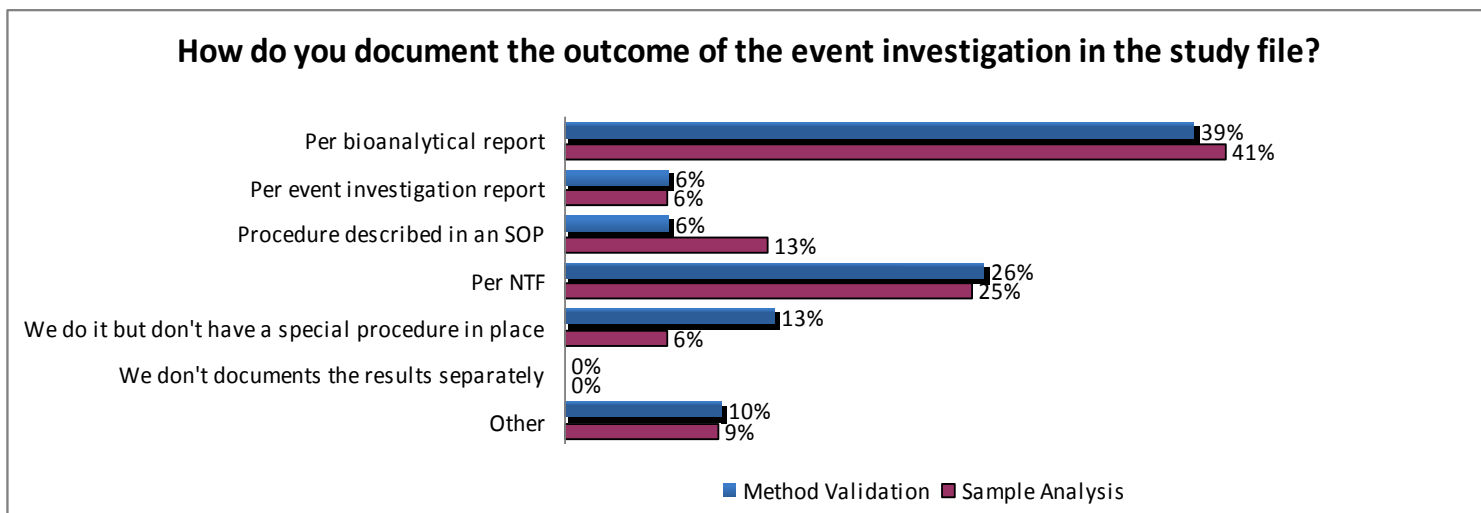
## ➤ Terminology

- Do you use the term anomalous results?  
Yes 6/22  
No 16/22
- “Unexpected results/events” seems to be the preferred terminology, 9/22

# Survey anomalous results - 2011

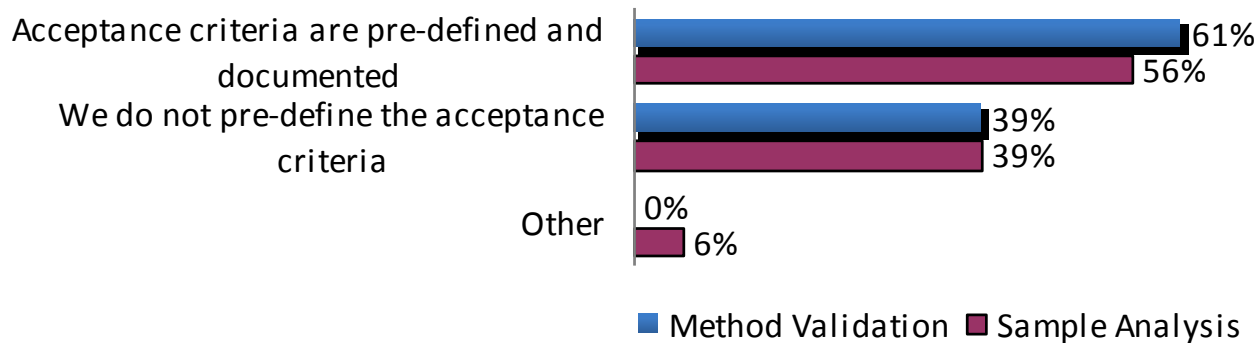


# Survey anomalous results - 2011



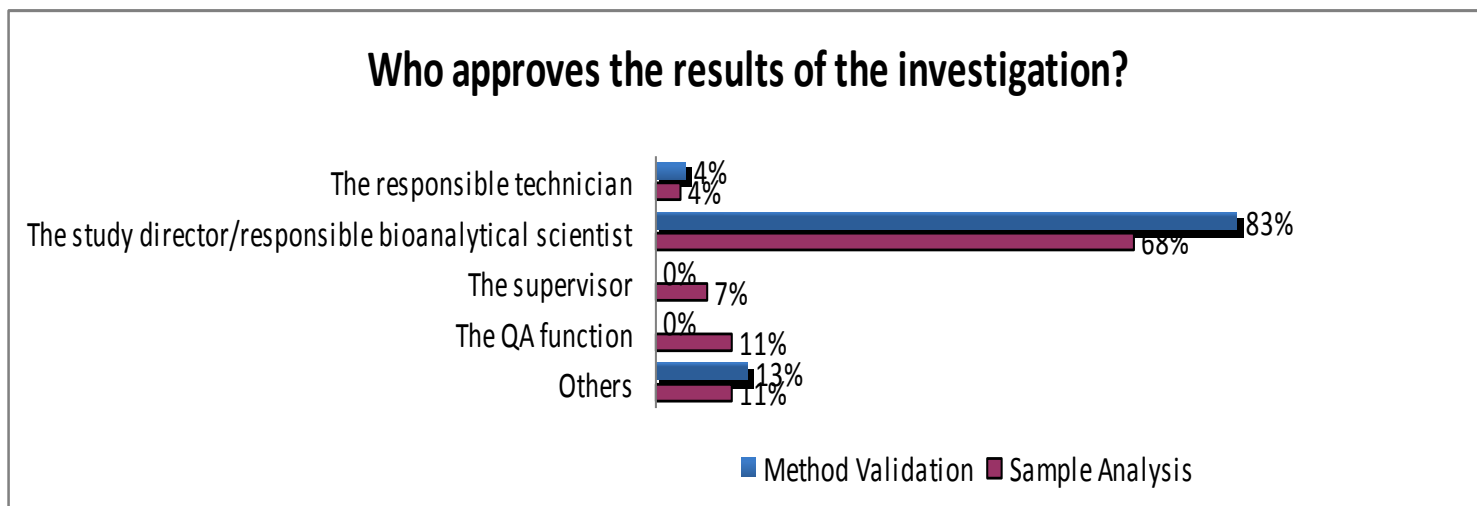
# Survey anomalous results - 2011

## Do you have special acceptance criteria established?

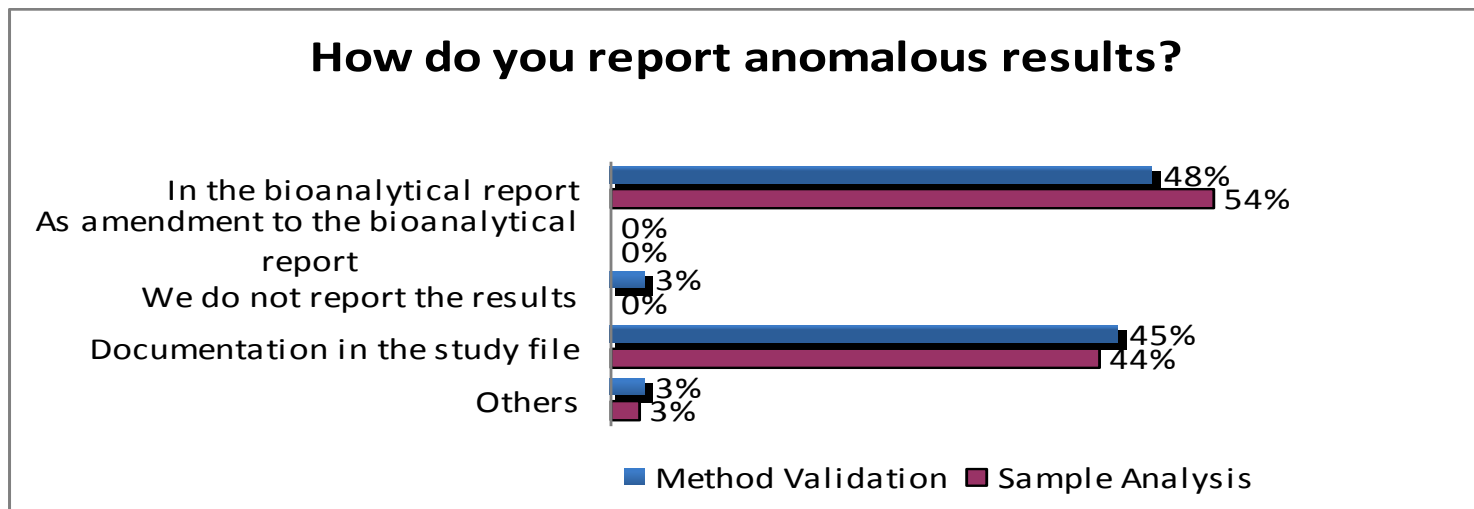




# Survey anomalous results - 2011



# Survey anomalous results - 2011



# Summary of the survey

- The results from the survey shows that the EBF member companies that responded to the survey
  - all handle unexpected results in some way, but it is obvious that there are several different ways of handling them
- No major change in results compared to last year's survey
- Good scientific practice established within EBF member companies - know-how and scientific expertise of bioanalyst can not be replaced by SOPs/CAPA documents
- But.....

# Are unexpected results solely an analytical problem?

- Further discussions within EBF initiated going beyond “accuracy/precision and robustness” of an assay
- Discussions are triggered by the EMA guideline on bioanalytical method validation where it is stated that

*The safety of trial subjects should take precedence over any other aspect of the trial. Consequently, there may be other circumstances when it is necessary to re-extract and/or re-analyse specific study samples, for example where an **unexpected or anomalous** result is identified that may impact on patient safety*

- It seems that nowadays the bioanalyst should not only assess the impact of the unexpected result on the analytical quality of the data but should also consider the impact on patient safety

# Acknowledgement

Thanks to

- All EBF members for input to the survey
- EBF TT-05

*Margarete Brudny-Klöppel, Sirpa Laakso, Magnus Knutsson, Peter van Amsterdam, Silke Lüdtkke, Susanne Globig, Nathalie Mokrzycki and Dieter Zimmer*