

Health Authorities Inspections: What to Expect? A Statistical Programmer Experience

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PHUSE EU Connect 2022
16th November 2022

Overview

 What is a regulatory inspection?

 Training and Preparation

 Cytel's Experience

 Challenges Faced

 Outcome and Conclusion

What is a regulatory inspection?



Health authorities routinely conduct inspections

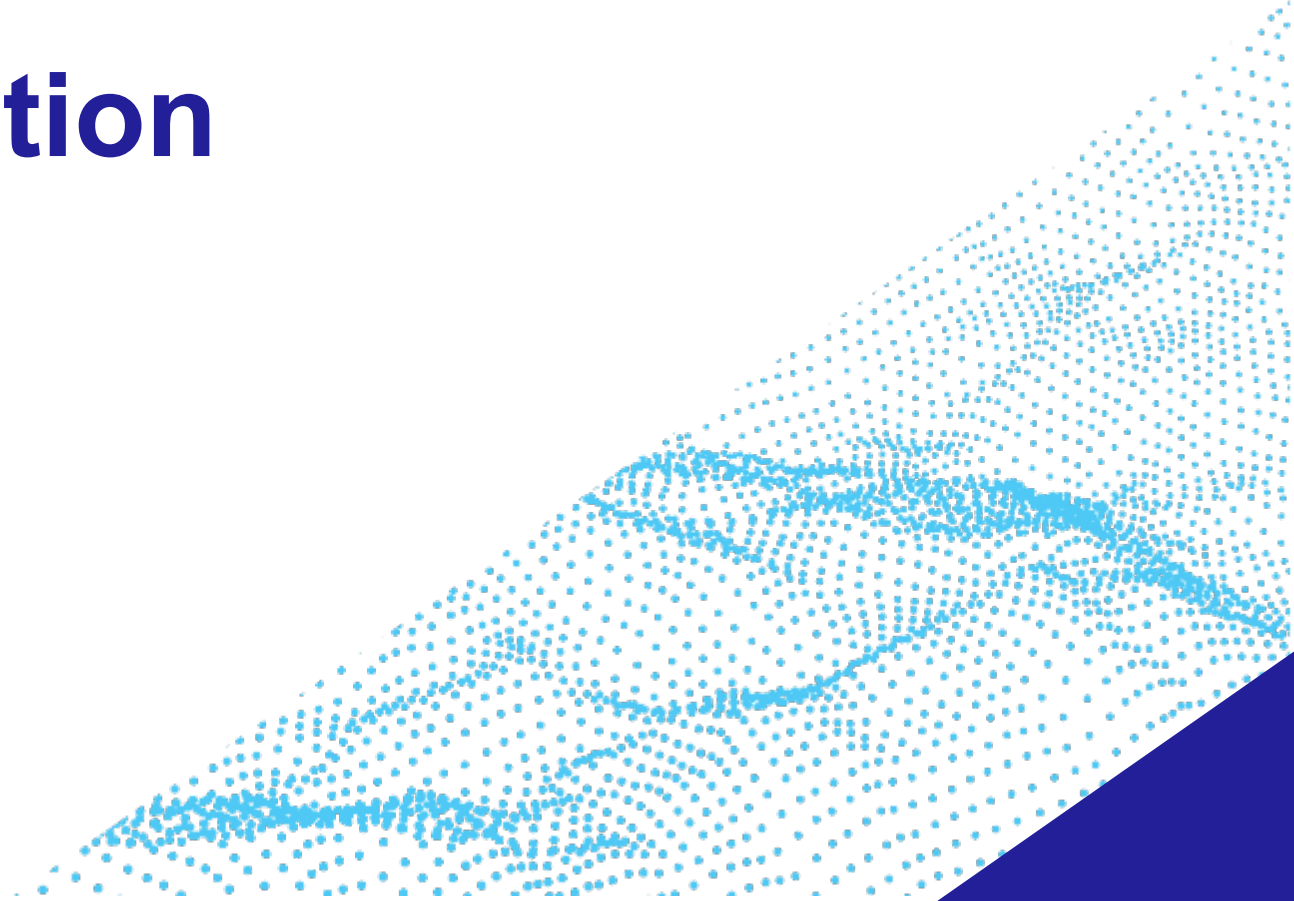
Integral to ensure safety and efficacy of products

Types of inspections

Audits vs regulatory inspections?



Training and Preparation



Company Process Compliance

❖ SOPs

- ✓ Have all study team members completed all required training?

❖ Project specific documentation

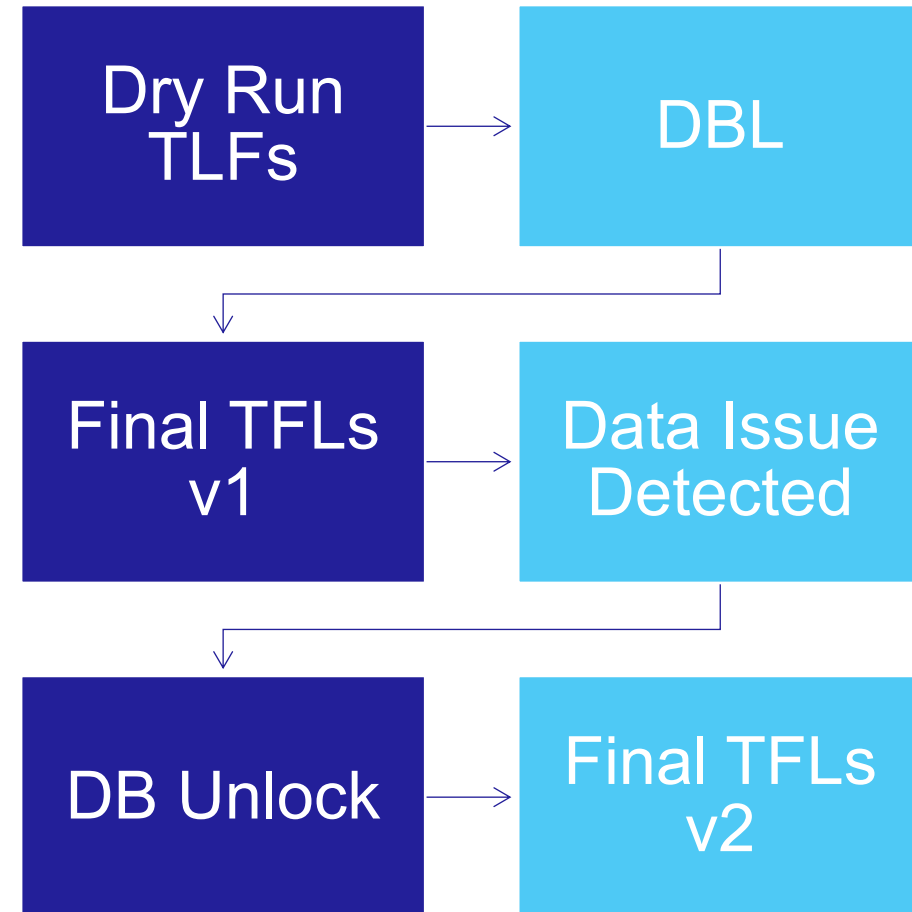
- ✓ Is there anything of particular interest that should be documented for this study?

❖ Sponsor SOPs or processes

- ✓ Does the sponsor have any training forms or processes you need to be compliant with?

Storyboards

- Map out all notable milestones of the project(s)
- Were there any key events to be aware of?
- Is it likely to be of interest to regulatory authority?



Interview Preparation



Don't speculate/guess

Be succinct/avoid imprecise language

Only answer the questions asked

Don't try to fill awkward silences

Mock Inspection

✓ Simulate real inspection

 Put into practice all training so far

 Requests

 Interviews

 Highlight any areas of further consideration



Cytel's Regulatory Inspection Experience



Nature and Process of the Inspection

➤ **Combined FDA and EMA Inspection**

- Held at the sponsor's site
- Duration of 2 weeks
- Remote Cytel participation

➤ **Biometric submission activities handled exclusively by Cytel**

- Identification of Cytel's line function representatives:
Data Management, Statistical Programming, Biostatistics, Project Management and Quality Assurance

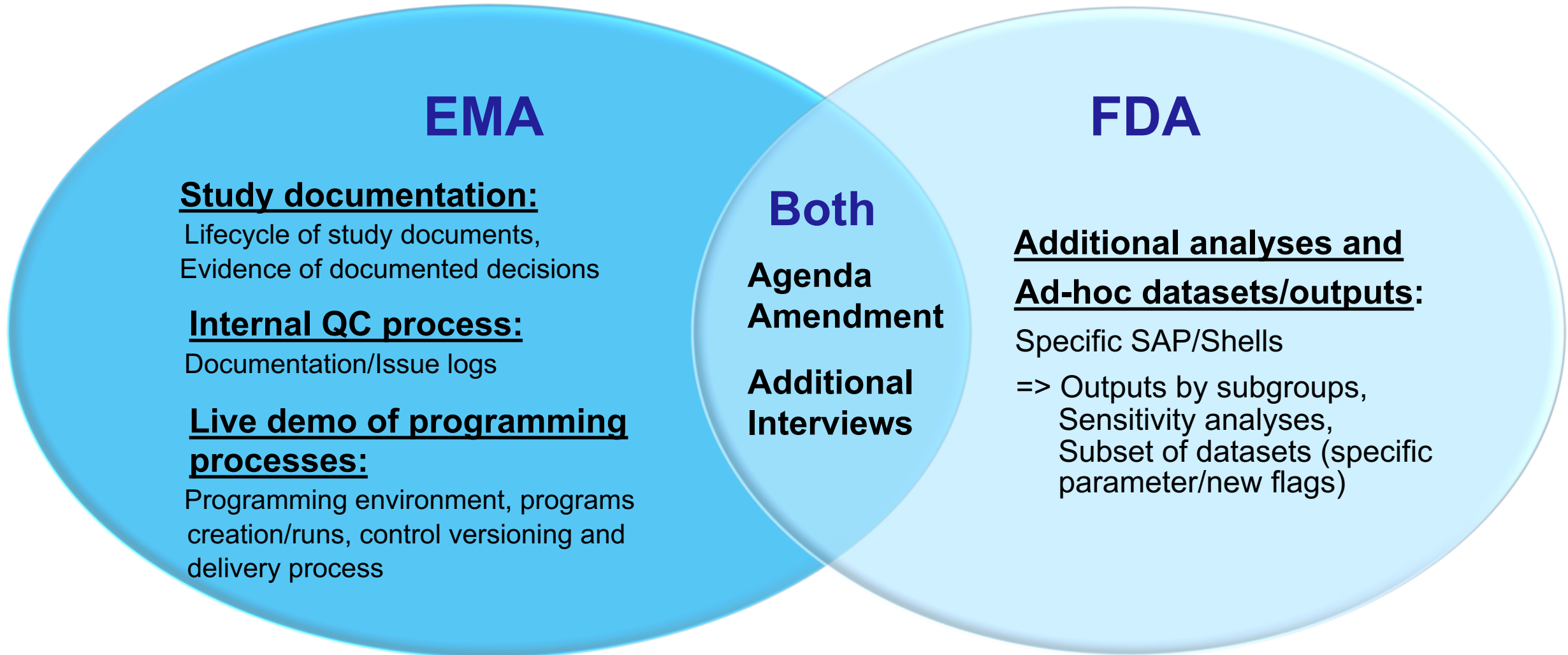
➤ **Release of the agenda prior inspection start**

- Information about planned topics of discussion and time of intervention

Process of Inspection (Cont'd)

- **Introductory session**
- **General overview of Cytel processes and services**
- **How were interviews scheduled?**
 - As per specified agenda
 - Requested on ad-hoc basis
- **How did we receive requests?**
 - Usually requested by inspectors during interviews
 - Potentially raised in other interviews
- **How were requests delivered?**

Requests and Expectations



Challenges Faced

Timeline

- Inspection was extended and longer than originally planned

Handling Multiple Requests

- Which takes priority?

Unpredictability

- Some events you cannot prepare for

Resourcing

- Problematic to handle multiple demands

Outcome and Conclusion

➤ **Findings**

- ✓ Could fall into several categories: minor, major or critical

➤ **No findings related to Cytel**

- ✓ Proves our processes work

➤ **Positive outcome for relationship with sponsor**

- ✓ Reinforced confidence in Cytel

➤ **Valuable learning experience**

- ✓ Both on a personal and company level

Thank you.

Cytel