Fluid-based Biomarkers

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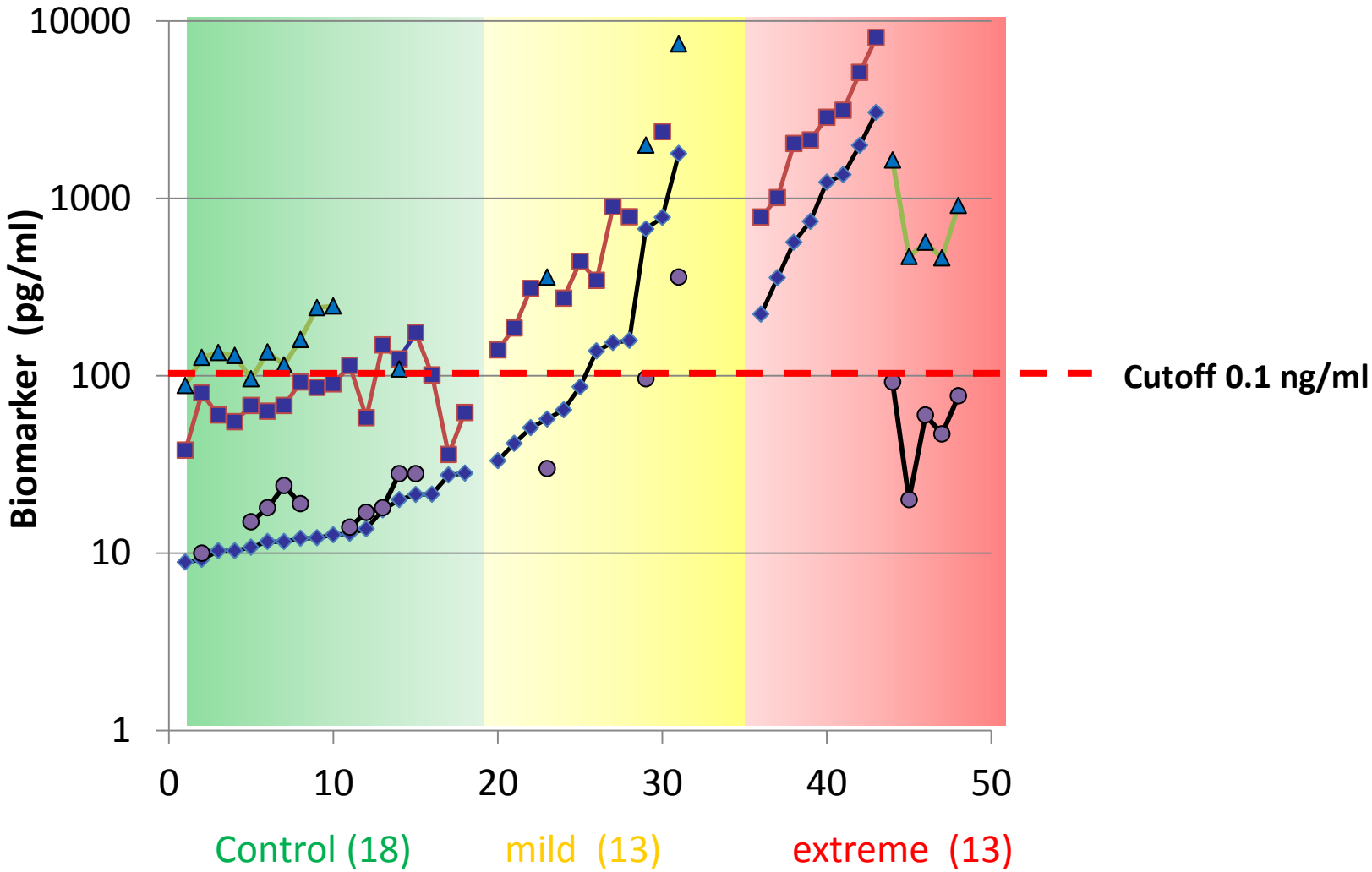
Biomarker and Assay are not identical



- **Need for assay standardization and fit-for-purpose validatio**

Summary : We have a come a long way ! – Essential elements for biomarker discovery and validation

- Standardization of analytics (pre- and post)
- Importance of fit-for-purpose concept and consensus on minimal analytical performance criteria (defined across disciplines) – evaluated by **independent** 3rd party
- Standardization of analytics (pre- and post)
- Generation of reference standards (troponin I, Aß1-42) – importance of orthogonal technologies
- Analytical performance standards in place for biomarker **qualification**
- Importance of core facilities (ADNI, PPMI)
- Publication/ Disclosure of these analytical performance criteria
- Clinical sample reference sets for assay harmonization and independent verification/validation sets matching intended use
- Most importantly, working together in a community of clinicians, research scientists and clinical chemists (and regulatory agencies) !

Questions for discussion :

- What are some examples of progress in developing standard protocols for fluid biomarker research?
- What are critical gaps in standardization that need to be addressed?
- Are the common data elements for fluid biomarker research sufficient? What are their limitations, if any? How does they compare to CDISC ?
- Where are you planning to store your biosamples for your InTBIR project?
- What are the strategies for open access to biorepositories and ensuring quality control ?
- What TBI repositories are available for fluid biomarker research and would it be advantageous to use them for InTBIR projects? Why or why not?
- Do the protocols for biomarker studies meet industry and regulatory requirements ?
- Are your InTBIR biomarker studies likely to lead to the development of TBI biomarkers as clinical diagnostics by 2020? If not, what would be required to meet this goal?