Increasing Challenges of Clinical Trials: Introduction

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on behalf of the EBF TT-12

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Typical Bioanalysis Conference Discussion

- Emerging Bioanalytical Techniques
- Emerging Bioanalytical Approaches
- Emerging Bioanalytical Regulations
- Ongoing Bioanalytical Issues
- Common Theme: Bioanalysis!

Introspective Orientation
Typical Bioanalysis Endpoint

- Provide Data to non-clinical colleagues
- Provide Data to clinical colleagues
- Provide Reports to regulatory colleagues
- Build, develop and maintain strong relationships with colleagues

Customer Focus
Bioanalysis / Clinical Interface: Some Potential Issues

- Clinical Protocol / Lab manual
- Concomitant Medication
- Informed Consent
- Equipment availability in clinic
- Sample Labeling
- Sample Handling/Collection
- Sample Shipment
- Data Transfer / Management
- Different regulatory requirements
- What about the Clinical perspective?

Bioanalytical Data Impact
Resolution

We must interact with our clinical colleagues to facilitate:

- Respect
- Understanding
- Two way Communication
- Quality
- Delivery on time

Pre-requisites of a High Performing Team
EBF interest in all this

- Show EBF desire to work together to optimize or solve some of the issues we identify
- Plan for and improve open communication and interactions with our clinical partners
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