

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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➤ Team members

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