



Bridging Science and Compliance

The Critical Role of Biometrics and Regulatory Affairs in New Drug Submissions

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Disclaimer:

Although I am often asked about planning data submissions, I am not a Regulatory Professional. This presentation is based solely on my own experience. Data submission decisions are very complicated and require written FDA agreement.

Introduction

Roles of Biometrics and Regulatory Affairs
in the New Drug Application (NDA) process

Importance of Collaboration

My Experience

Key Takeaways and Lessons Learned

Biometrics

Data Management

Data Standards

Programming

Biostatistics



Ensure products are safe, effective, and of high quality by enhancing data quality, definition, analysis, and reporting



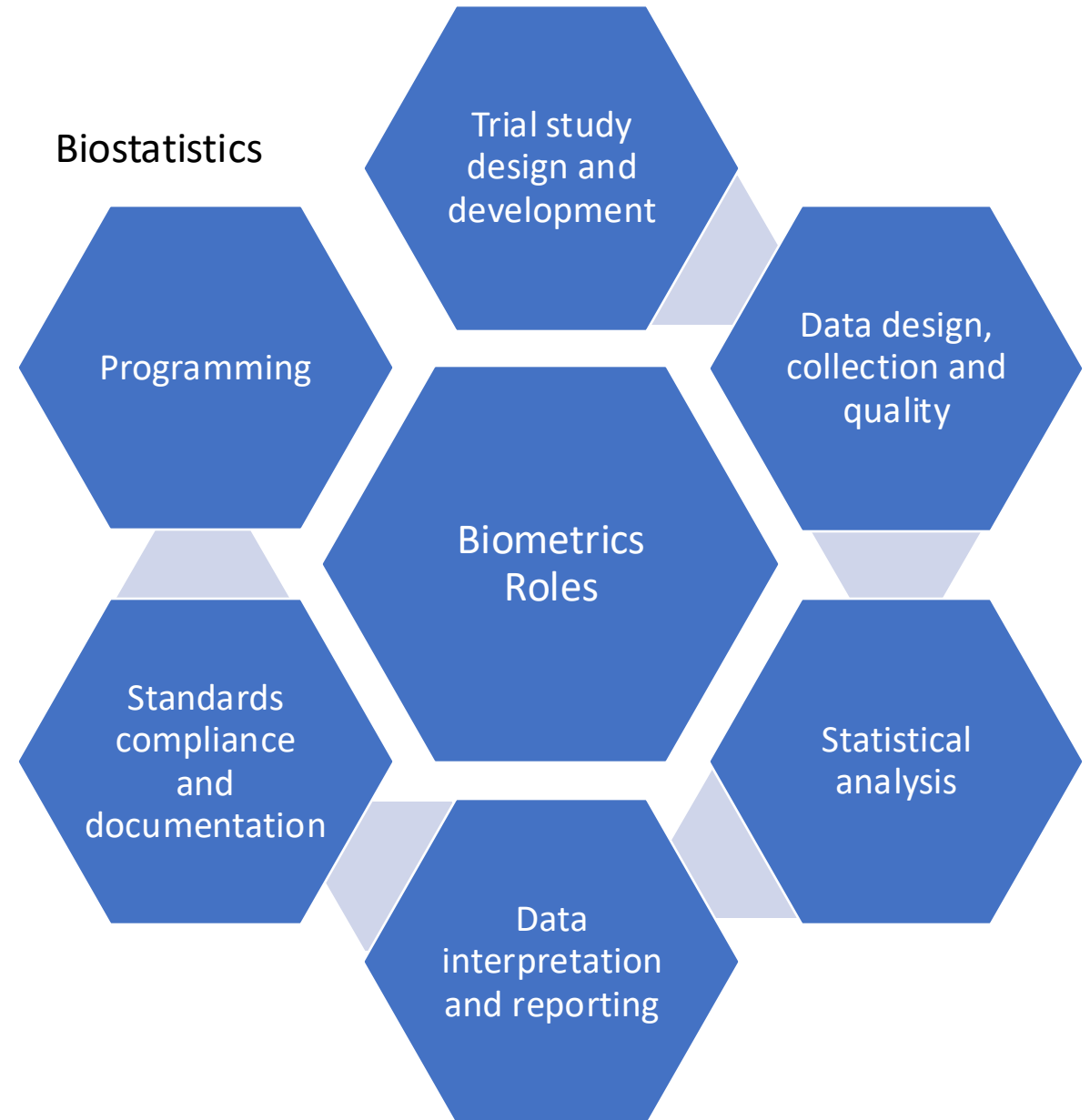
Submission Strategy:
Structure data submissions for traceability, clarity, and compliance



Compliance with regulatory guidelines:
Study data standards and technical conformance



Agency Interactions:
Respond to queries by providing data, analysis, and directed documentation



Regulatory Affairs

Strategy & Operations

Labeling

Publishing & Submission



Ensure that products are safe, effective, and of high quality by enhancing the strategy and compliance of regulatory submissions



Compliance with regulatory guidelines: FDA, EMA, and ICH requirements as well as country specific rules



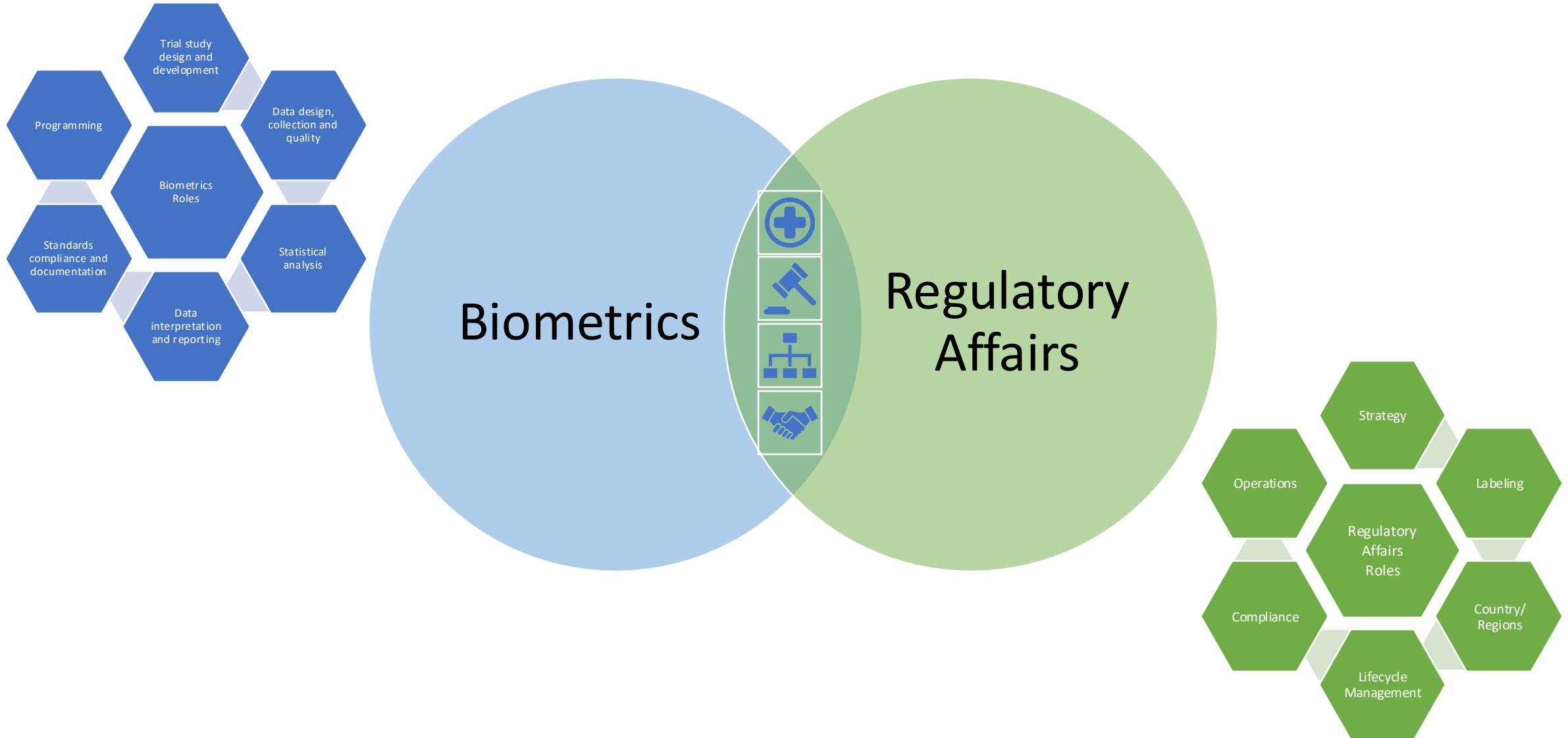
Submission Strategy: Structure applications for efficiency and compliance within the eCTD



Agency Interactions: Respond to queries and mitigate regulatory risks



Overlapping Goals with Complimentary Roles



Why Collaboration Matters

Developing	Developing regulatory documents and packages that are timeline critical (i.e. SDSP, BIMO, RGs, and defines) and require cross-functional review
Strategizing	Strategizing for any atypical data or documents and their place in the eCTD
Ensuring	Ensuring data accuracy and compliance with submission requirements
Aligning	Aligning statistical outputs with regulatory expectations
Addressing	Addressing potential data inconsistencies proactively
Crafting	Crafting robust responses to Health Authority Information Requests

My experience

When I was hired by a:

- Biostatistics Department
- Regulatory Affairs Department
- Chief Medical Officer
- CEO



Challenges in Collaboration

- Differences in priorities and perspectives
- Evolving regulatory standards and analytical methods
- Data structuring and standardization (CDISC, ADaM, SDTM)
- Understanding terminology specific to subject matter experts
- Acknowledging the boundaries of your expertise
- Transparency across silos
- Acceptance of feedback from other functional experts

Best Practices



Early engagement between
biometrics and regulatory affairs



Clear communication and shared
understanding of regulatory
requirements



Use of cross-functional review
processes to ensure consistency
and completeness



Openness and kindness



Final Thoughts



Biometrics ensures data integrity and statistical rigor



Regulatory affairs ensures compliance and strategic submission planning



Both groups work towards the efficacy and safety of products



Shared setting of compliance, strategy, and accountability to health authorities



Strong collaboration enhances approval success and patient access to treatments



Questions, Comments,
and Stories



THANK
YOU!

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