Winning FDA Approval: How to Build Your Product & Beat your Competition with Analytics

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Julia E. Seaman, PhD
Isabel Elaine Allen, PhD

Bay View Analytics®

About Us

Isabel Elaine Allen
Senior Advisor

Julia Seaman
Director of Research

Statistical and Scientific Expertise

Core projects cover all stages of biopharmaceutical project development, and our experience runs the gamut, from early leads generation, pre-clinical and clinical trial designs, regulatory submissions, and late-stage commercial products.

We work with all facets of the biotech and biopharmaceutical industry, such as diagnostics, devices, digital apps, and therapeutics.

Recent Biotech/Pharma Consulting Projects:

- Lead generation using genomic and proteomic data.
- Proof of concept experiments.
- Clinical trial design, sample size, power, and statistical plan writing.
- Clinical trial data analysis and methods write up for publications and regulatory submissions.
- Meta-analyses to accompany an FDA submission for a new indication.
- Machine learning, AI, LLM, & other analyses of EHR data to develop devices and diagnostics
- SBIR, NIH, PCORi and NSF grant writing assistance.
- Expert witness testimony for a global diagnostic company and biotechnology companies.
- HIPAA compliant data transfer and analysis for a dermatologic therapeutic and for an AI diagnostic
- Design of a trial for a registry of patients

Let's start with some available data: How long does it take from idea to market*?

Clinical Therapeutic: 10-15 years
Clinical Therapeutic for Animals: 3-6 years
Class III Medical Device: 3-10 years
Class II Medical Device: 2-5 years
Soft Drink: 3 years
Software Package : 1-3 years
Digital App: 18-30 weeks
Daycare Center: 6 months
Hot Dog Stand: 60 days
Sole Proprietorship/Services: 0 – 1 day

*H.Balakrishna, U.Cincinnati

WHAT DO YOU NEED DATA FOR?

In the beginning…

- Investors
  - Friends & Family
  - Angel investors
  - Venture Money
- Grants & other support
  - Start-up incubators
  - SBIR
  - Foundations
- Patent lawyers

And then…What else to you need data for?

- The FDA Journey
  - Phases
  - QA/QC – Engineering
  - Hipaa rules/Privacy
- Marketing
  - Getting on the formulary
  - Getting into the OR
  - Getting onto a smartphone
- Patent lawyers

WHAT KIND OF DATA SHOULD YOU COLLECT?

- Data comes in many levels: nominal, ordinal, interval, ratio
- Metrics are important but consistency and spread are more important. Investors will care more about your variability than your average performance* - consistency, reliability, reproducibility*
- Duration of use, amount of use, & how many users will drive your digital health app
- Charts always win over tables – but don't get creative with your axes
- And don't get creative with your statistics (change, percent change, relative change, relative percent change, fold change, …)**

**2004, 2009, 2012 StatTools in Quality Progress*
***2015, StatTools in Quality Progress*

WHERE WILL YOU NEED THIS DATA?

- Proof of concept
- Understanding competitors – what is the state of the art right now?
- Assay Validation – what is your CV?
- Due diligence
- Engineering specifications - what goes into your device?
- Ease of use – training time?
- In vitro models
- Pre-clinical/Animal models/drug delivery
- Diagnostic accuracy / sensitivity / specificity
- Clinical trials (that FDA end of Phase II meeting)
- Beta testing your app
- Manufacturing specifications
- Digital users – the GUI
- Compliance – are you using rfd tagging?
- Quality Control – shipping/shelf life/heat/cold…
- Quality Assurance

…Everywhere

WHAT SHOULD YOU DO WITH THIS DATA?

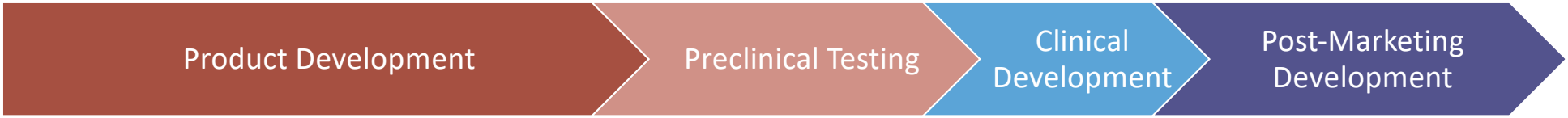
- Protect it
- Don't talk about it
- Don't publish it
- Don't share it
- *Always* get an NDA
- Patent Attorney
- Continue to Innovate

CLINICAL DEVELOPMENT IS NOT ISOLATED FROM THE BUSINESS DEVELOPMENT

Regulatory Actions:

Initial FDA conversations

510(k), PMA, or De Novo Application



Research Actions:

- Market identification
- Model refinement
- Laboratory and animal studies
- In-human clinical studies

Business Actions:

- Funding
- Company growth
- Skills Development
- Funding
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- Clinical and manufacturing skills growth
- Funding
- Competitive Intelligence
- Commercial skills growth

The results and details of clinical development directly affect business development, which then directly affects capabilities for clinical development

DATA ARE INTEGRAL THROUGHOUT THE PROCESS

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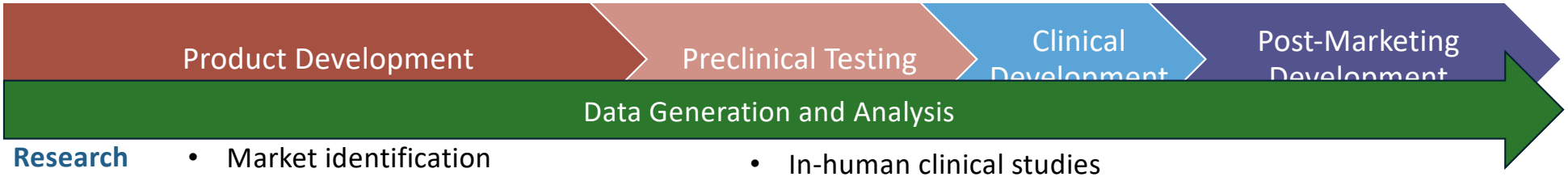

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QUESTIONS YOU WILL NEED TO ANSWER (IDEALLY BEFORE YOUR FIRST FDA MEETING):

- Do you have a **predicate**? More than one?
- Is there a **gold standard** (i.e.; biopsy? nodes identified?) or **comparator**?
- When should you start **gathering data**?
- Will you need a **clinical trial** of comparison? Will it need **HIPAA compliance**? **IRB** approval?
- What are you evaluating? **Endpoints**?
  - How will you measure your endpoints? Are they continuous or categorical?
- Is this an **AI and/or digital** device/algorithm/diagnostic or physical tool?
- Have you developed a **protocol** for your evaluation? A **statistical analysis plan (SAP)?**

PROOF OF CONCEPT IS A KEY TEST FOR ANY PRODUCT

Proof of Concept (PoC) is a demonstration in principle with the aim of verifying that some concept or theory has practical potential or an idea or method is feasible

Can the product be developed?
Does the product work?

Proof of Concept Objectives in Health

- Validation of the relevance of your therapeutic or diagnostic in pre-clinical & early clinical tests
- Defining your potential market
- Show early evidence of clinical efficacy
- Eliminate blind alleys/failures early
- Provide an assessment of commercial potential

Some more notes on PoC

- PoC is not just one experiment at one time; you can have multiple PoCs during development
- PoC is different for different types of products
- Think of PoC as part of the exploratory science and have a checklist of what you need to show
- Realize that therapeutic/diagnostic studies may be valuable even if they have low power
- PoC should include estimates for market size & potential growth if you are looking for $$

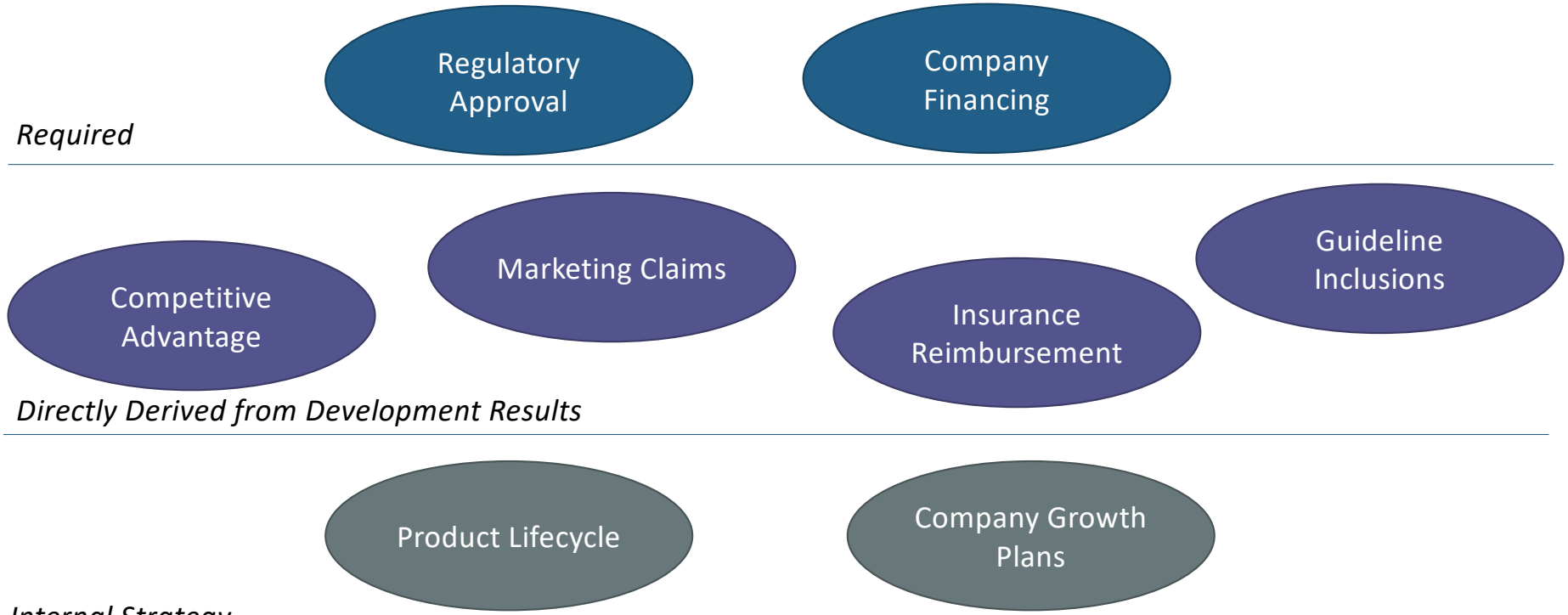
Don’t undertake PoC studies (or any studies) unless you understand how you might use it to change or even cancel a project

PROOF OF CONCEPT = PULL OUT CHECKBOOK $$$

Everyone looks for something different from a PoC

Type	Devices & Diagnostics	Digital Health, Health Apps, & mHealth	Therapeutics
Angel Investors	Prototype & preliminary in-vivo or retrospective testing	Prototype, algorithm, 'vaporware', market opportunity	Publishable data describing efficacy & small animal testing and to support a provisional patent application
SBIR	Animal testing or in-vivo testing to show comparability to existing devices	Demonstrate need, user interface, comparison to non-digital solution	Supports pre-clinical research aimed at discovering & optimizing lead molecules
Investors, Partnerships, and Regulatory	Working device & sensitivity, specificity, equivalence, enough in-vivo data for comparisons	Beta testing, effectiveness compared to non-digital solution, Engagement, Retention	Establish the safety of drug/biologic candidates in the target population and explore the relationship between the dose and the desired outcome.

What can a PoC influence?



YOU NEED A DEVELOPMENT PLAN FOR PoCs

- Work backwards
- Develop your plan from molecule/NCE through approval
- Identify costs, timelines, clinical trial designs
- Incorporate clinical trial designs into pre-clinical model

(i.e.; prophylaxis vs. treatment models)

- Use the plan daily to ensure consistency and compliance

Remember: **Approval is the bare minimum**! You still need a competitive product to continue to succeed.

Think forward – plan for **what will be required**, not what is currently.

Plus, it is **impressive to potential investors ($$)** to have this plan.

SOME QUICK ANSWERS AND ANALYTICS THOUGHTS (1):

- What kind of data should you gather and why?
  - Proof of concept experimental data
    - Publish, patent, early test of endpoints
    - Raising capital, joining an incubator, presenting to Rosenman
  - FDA first/second/etc meeting
    - Show proposed endpoints
    - Calculate required sample size and power (!!)
    - Identify appropriate statistical analyses for submission
    - Create your initial protocol and SAP

SOME QUICK ANSWERS AND ANALYTICS THOUGHTS (2):

- What about your statistical analyses?
  - Sample size and power
    - Do you have one or several primary endpoints?
    - Showing you are superior to the predicate or 'substantially equivalent'?
    - Identifying any subgroups or covariates that are important
  - Primary analysis and SAP (Statistical Analysis Plan)
    - How is it different than the protocol
    - Is there one or several primary analyses (i.e.; Deming regression & Bland Altman)
    - Are you planning an interim analysis?
    - What are the testing hypotheses and/or performance thresholds?

SOME QUICK ANSWERS AND ANALYTICS THOUGHTS (3):

- Most common endpoints and differences between them:
  - Continuous (Measurement) outcome
    - Paired or unpaired hypothesis test?
    - Inclusion of important covariates?
  - Categorical (Positive/Negative) outcomes
    - Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value
    - AUC (Area under the curve)
    - Deming Regression
    - Bland-Altman Analysis

CASE STUDY #1: IMVARIA AI ASSISTED DIAGNOSTIC FOR ILD & IPF

Bay View Analytics continues to work with Imvaria on new products for their design and analytics

- Background: AI algorithm to identify Lung Fibrosis (FIBRESOLVE) and screening tool (SCREENDX)
  - No cure exists, biopsy has 25% mortality rate and MD sensitivity for diagnosis ~ 30%
  - Imvaria is a Rosenman company
- 9-12/2021– Design protocol and Statistical Analysis Plan (SAP) for FIBRESOLVE
  - Feasibility analyses on 50 cases
  - Identify subgroups and primary endpoints – Sensitivity/Specificity/AUC
  - Calculate required sample size and power for the pivotal trial
- 1/2022 – FDA Meeting to discuss pivotal trial and endpoints for FIBRESOLVE
  - FDA Meetings 6/2022 & 8/2022 with FIBRESOLVE approval 9/2023
  - Next steps: Post-marketing study of 150 IPF cases
- Simultaneously publishing results of FIBRESOLVE study in *Diagnostics* in 4/2024 and meeting with the FDA on SCREENDX with SCREENDX approved 3/2024
- Currently working on design, sample size & power, and SAP for BRONCH AI to identify nodes
  - Multi-screeners, multi-reading, multiple cases

IMVARIA

CASE STUDY #2: RETI-TRACK DEVICE FOR MEASURING EYE MOVEMENT

- Background: Oculometrics for Healthcare - Advanced motion pattern, longitudinal tracking, compact device
  - Piloted at UCSF, funded partly by the Alzheimer's Foundation
- 6/2022 – Developing the protocols and SAP for 3 pivotal studies
  - Pupil and retinal tracking, Intended use validation, Motion extraction verification
  - Endpoints for frequency and amplitude Intended use validation
  - Accuracy, repeatability, & reproducibility (sensitivity, Bland-Altman, Deming regression)
  - Trial using 3 devices, 3 operators, 14 signal enpoints tested 3x by each operator
- 11/2022 – Initial FDA Meeting to discuss protocols and endpoints
  - 3/2023 – Responses to FDA and filing 501c3
  - 5/2023 – Reti-Track approval
- Currently a waiting list for installation – new clinical trials in Parkinson's disease and applying Reti-Track to eye movement in athletes
- Working on several publications

C. LIGHT TECHNOLOGIES

https://www.clighttechnologies.com/

ADVICE FOR GETTING APPROVAL

- Know and trust your product!
  - Statistics are just a small (but critical) section
  - Don’t design to a test
- FDA submissions are more like debates than tests
  - If you are arguing stats, it may be too late
- Be careful that medicine and healthcare are not black and white, but statistics can be

What are your questions?
How we can help you?

Julia@bayviewanalytics.com

Isabel@bayviewanalytics.com

Bay View Analytics®

LinkedIn