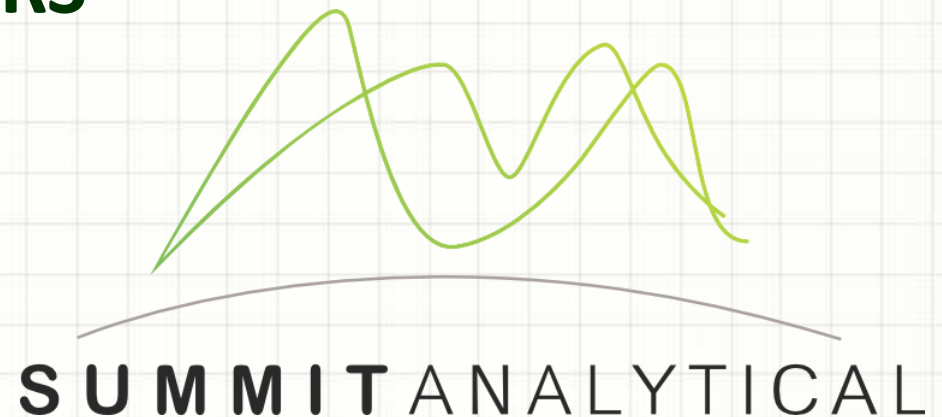




A VISION FOR THE FUTURE: CORE COMPETENCIES FOR STATISTICIANS AND STATISTICAL PROGRAMMERS



James R. Johnson, PhD
Summit Analytical, LLC
2014-10-12



Welcome

Overview of Topics in Presentation

1

- Science of Drug Development is Multi-disciplinary

2

- Staff, Skills, and Knowledge

3

- Development of Statisticians and Statistical Programmers

Economics and Probability

~ 250 to 300
Million USD

Probability

Costs

Probability
of Success

1/10,000

Total
Cumulative
Costs

Target
ID

Medicinal
Chemistry

Pre-
Clinical
Dev

Phase I

Phase II

Phase III

Regulatory
Review

Indefinite

~3 yrs

~3 yrs

~1 yr

~2 yrs

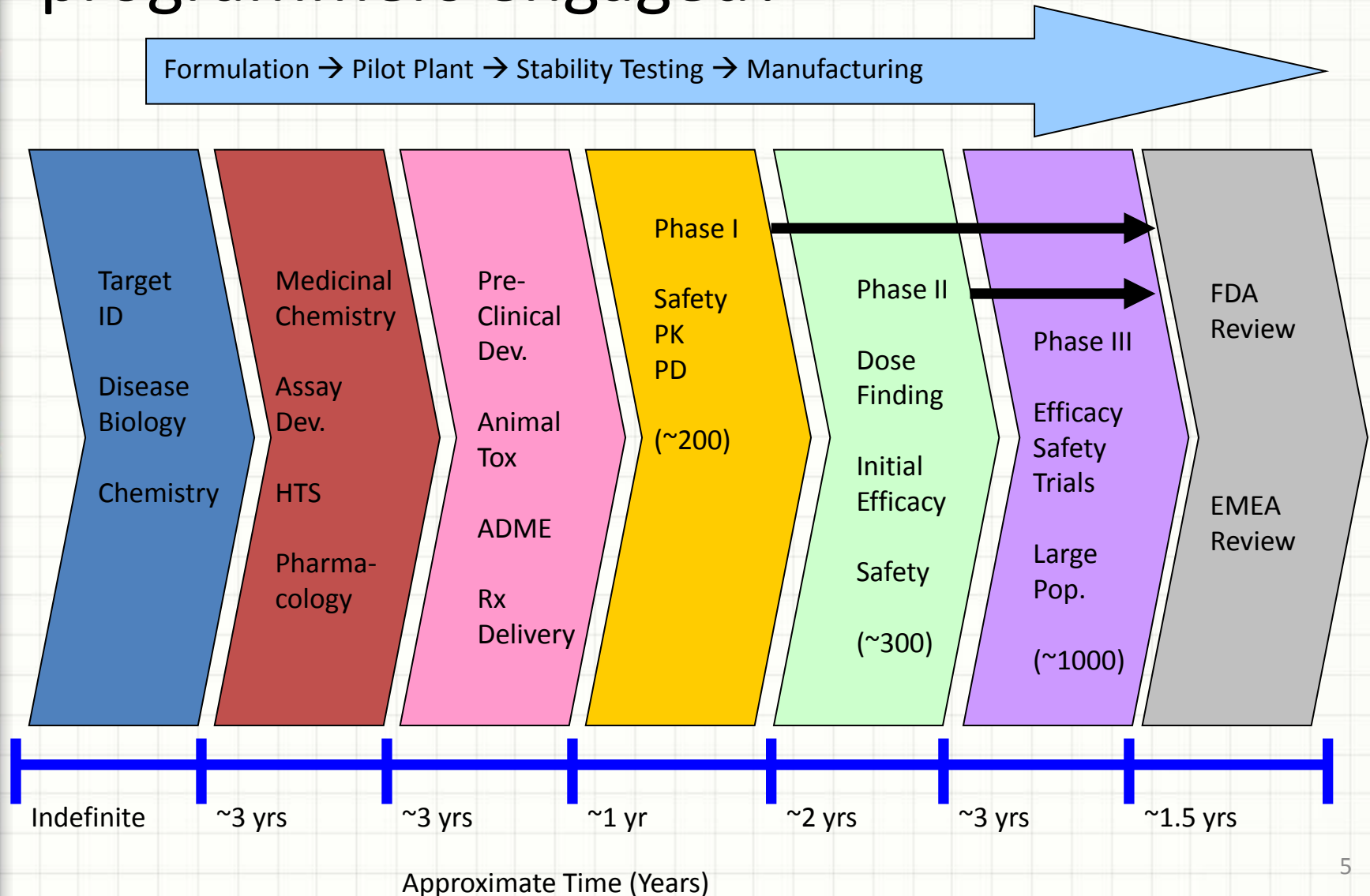
~3 yrs

~1.5 yrs

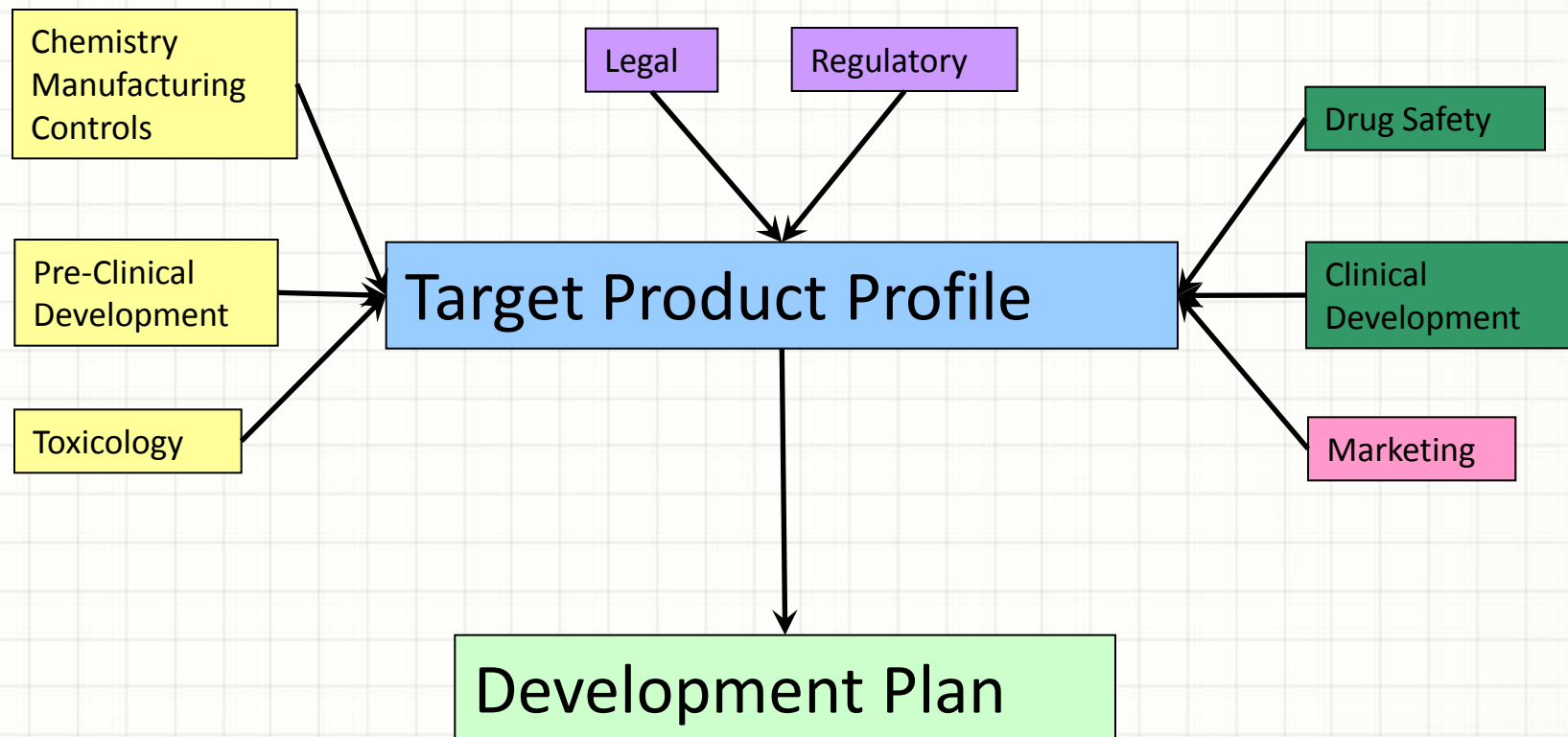
Approximate Time (Years)



Where are Statisticians and Statistical programmers engaged?



Statisticians / Statistical Programmers work across all disciplines in drug development.



10 year Vision

- Broad core knowledge base and competencies for statisticians and statistical programmers
- Added exponential value of statistician and statistical programmers to product development teams.
- Improve quality and delivery of statistical sciences (includes epidemiology, health outcomes, market access, clinical effectiveness)

A Career --- Not Just a Job!

- A fundamental shift for CROs and Sponsors MUST occur that treats the development of core competencies as part of career development.
- Statistician and Statistical programmer expectations and long term vision for career development starts with Management Communication and Mentoring.

Recruiting Statistics (Real Costs!)

- Median (range) Recruiting Costs as percentage of salaries offered for:
 - Statisticians: 12.4% (9.1% - 28.3%)
 - Statistical Programmers: 11.6% (8.7% - 19.9%)
- Median (range) Time to Hire (Months):
 - Statisticians: 12.3 (2.6 – 23.9)
 - Statistical Programmers: 7.1 (1.2 – 20.8)
- Data from a sample of 7 Pharmaceutical companies and 6 CROs (Years: 2013-2014)
- Recruiting is expensive and Time Consuming!

2010 to 2013 Staff Turnover Rates (USA Data)

- Median (range) Turnover rates are Voluntary Numbers who Leave a Company:
 - Statisticians: 13.3% (8.4% - 17.1%)
 - Statistical Programmers: 16.6% (7.1% - 29.5%)

Data Limited to Statisticians and Programmers working in Healthcare Research.

Median Staff Retention Time

- Median (range) Retention Time (Years):
 - Statisticians: 4.6 (0.8 – 24.3)
 - Statistical Programmers: 3.1 (0.2 – 20.3)
- Significantly High Regional and Geographic Variability.
- Data from a sample of 7 Pharmaceutical companies and 6 CROs (Years: 2013-2014)

Primary Reasons for Turnover

- Top 5 Broad Categories for Statisticians or Statistical Programmers Turnover in order of Importance:
 1. Immediate Management Support
 2. Work / Life Balance
 3. Development and Career Advancement
 4. Company Culture
 5. Salary and Benefits

Why Develop Careers

- #1 -- Reduces turnover and recruiting costs!
- #2 -- Improves Overall Quality of Work Products across all development stages.
- #3 -- Improves team productivity and efficiency in development and delivery of work products.
- #4 -- Provides individuals with a vision and goals to personalize their own career development.

Skill Levels for Consideration

- Over an approximately 15+ year career timeframe a statistician or statistical programmer will move through:
 - Beginner
 - Intermediate
 - Advanced
 - Expert
 - Expert – Consultant
- Each person will move through these stages at different rates based on their individual goals, attitude, and passion for self-development.

Beginner

Beginner / Basic	A person who has just started to do or learn a skill; novice; limited experience, exposure, or expertise; expectation is a beginner or basic skills requires learning and comprehension time to achieve desired skill level. A beginner will also require a large amount of mentoring and coaching for skills development.
---------------------	--

Intermediate

Intermediate	A person who has limited experience, exposure, or expertise and is not a novice with the task (or skill); expectation is intermediate skills require continued learning and comprehension with less time to achieve desired skill level. This level of person also has the ability to learn from recall and stimulate additional ideas to solve problems.
--------------	---

Advanced

Advanced	A person who has highly developed experience, exposure, or expertise with advanced problem solving skills and comprehension of the desired skill. Expectation is advanced skills require continued learning and comprehension for complex or novel skill sets. This level of person also has the ability to learn from recall, stimulate additional ideas to solve problems, and is able to serve as a mentor to communicate and solve problems.
----------	---

Expert

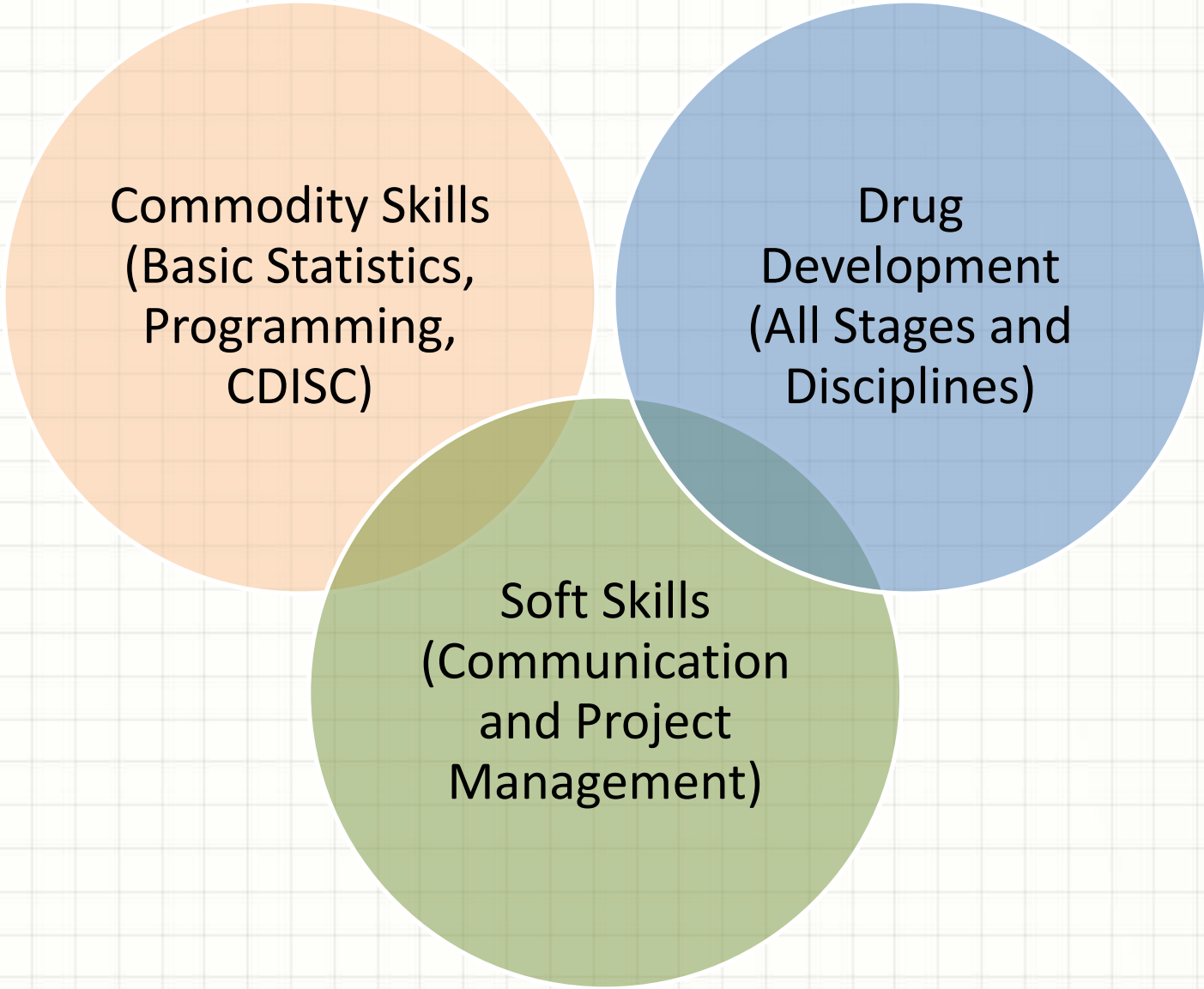
Expert

A person who has demonstrated and is widely recognized as a reliable source for skill and technique and whose faculty for sound judging and decision making and problem solving is accorded authority and status by their peers. An expert, more generally, is a person with extensive knowledge and ability. Experts are called on for advice on their respective subject matter. Experts require limited time to learn new or enhance existing skills.

Expert - Consultant

Expert - Consultant

A person who has significantly demonstrated and is widely recognized as an expert and experienced source for skill and technique; has significantly demonstrated sound judgment, decision making and problem solving skills in a collaborative environment and is accorded authority and status by their peers. An expert – consultant is also a person with extensive knowledge, expertise and abilities with broad ranges of experience and exposure in their field(s). Expert - Consultants are mentors, teachers, coaches and facilitators who are called on for advice on their respective subject matter. Expert-Consultants require limited time to learn new or enhance existing skills.



Commodity Skills
(Basic Statistics,
Programming,
CDISC)

Drug
Development
(All Stages and
Disciplines)

Soft Skills
(Communication
and Project
Management)

Core Knowledge Base

- Commodity Skills and Knowledge:
 - Statistical Programming (SAS, R, etc.)
 - CDISC (SEND, CDASH, SDTM, ADaM)
- Commodity skills are expected and part of the basic skill sets required of Statisticians and Statistical Programmers.
- Commodities are tools of the trade!

Core Knowledge Base

- Drug Development Knowledge Base
 - Clinical Trials Design and Analysis Expertise
 - PK/PD trials
 - Safety and Efficacy trials
 - Clinical Effectiveness/Market Access trials
 - Regulatory Submissions Expertise
 - Pharmaceuticals (CMC) Expertise
 - Pre-clinical, Animal Toxicology, ADME Expertise

Soft Skills and Experience

- Communications Skills
 - Written and Oral
- Problem Solving Skills
- Project Management Skills
- Time Management Skills
- CRO and External Vendor Collaboration and Management Skills (Sponsors)
- Must have skills for successful and valuable Statisticians and Statistical Programmers

Drug Development Outline

- Consider training Modules on:
 - Introduction (Rx, Design of Drugs)
 - History of Clinical Research, Drug Development
 - Pre-Clinical Development
 - Pharmaceuticals and Manufacturing
 - Clinical Development
 - Clinical Trials Design & Analysis
 - Regulatory Sciences

Should PhUSE provide a training and development program to Advance a 10 year Vision ?

- A fellows program?
- A certificate of training program?
- Broad based and international in focus?
- Provide a Valuable and Respected Life-Long Learning Career Development Tool for Statisticians and Statistical Programmers?

Thank You – Questions/Discussion



Contact Information

James R. Johnson, PhD
Sr. Principal Consulting Biostatistician
Summit Analytical, LLC
104 Lutterworth Court
Cary, NC 27519-8682 USA
Email: jjohnson@summitanalytical.com