



Statistical Programming 101 for the Fourth Industrial Revolution

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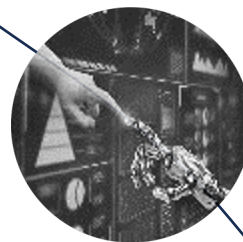
Ritika Aggarwal
Statistical Programmer

 NOVARTIS | Reimagining Medicine

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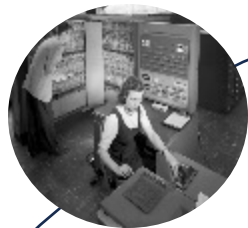
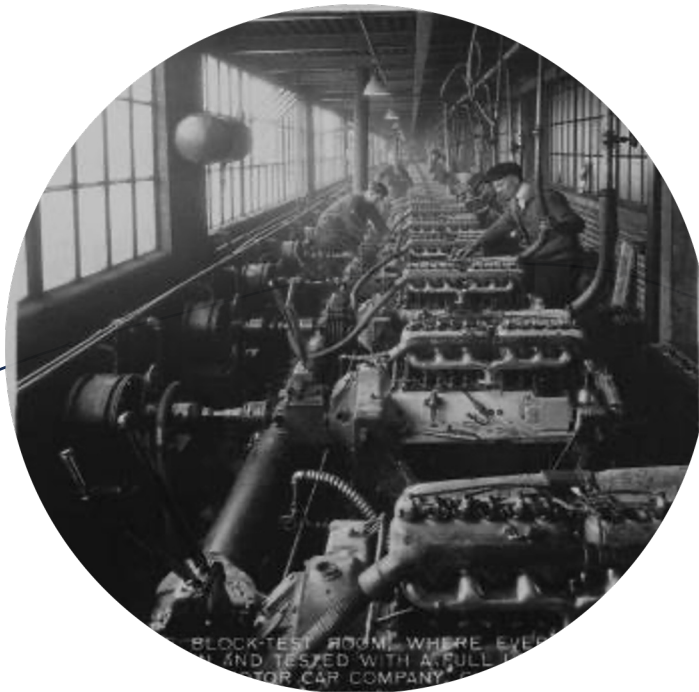
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First Industrial Revolution



Steam propelled

Second Industrial Revolution



Electricity Powered

Third Industrial Revolution



Preliminary automation and machinery engineered

Fourth Industrial Revolution



Cyber-physical systems

Pharma 4.0

Key Elements

Big Data Analytics

Electronic health records and patient reported data, wearable sensors data, specialized central labs.

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Cloud Computing

Enables collaboration and data sharing across the pharmaceutical industry, resulting in efficient drug discovery and development.

Data lies at the heart of Pharma 4.0

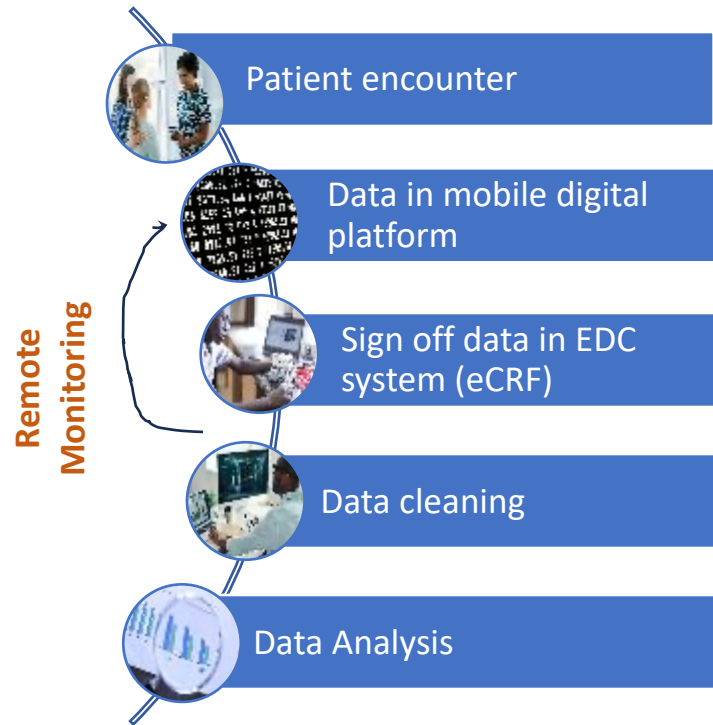
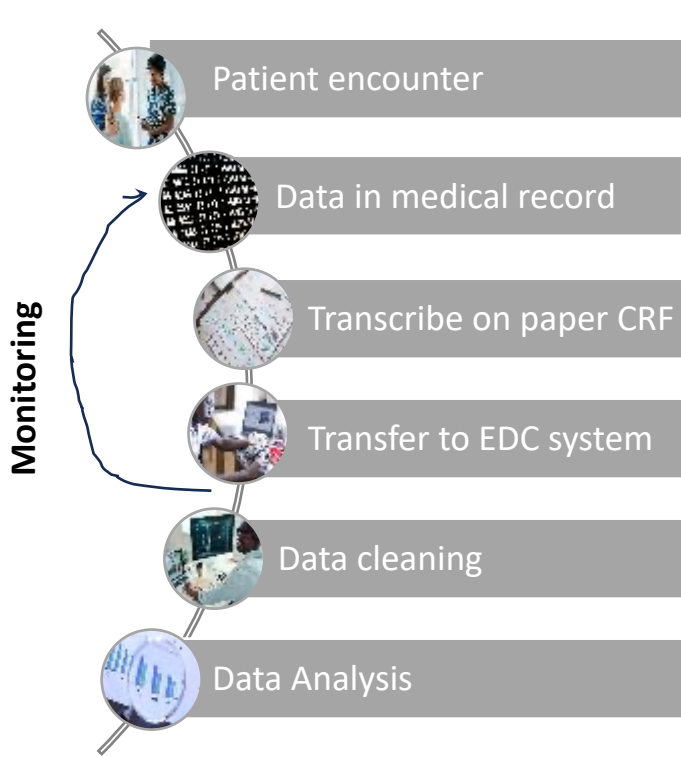
Novartis Pharmaceuticals collaborates with Qualcomm in digital innovation with the Breezhaler(TM) inhaler device to treat COPD

Jan 05, 2016

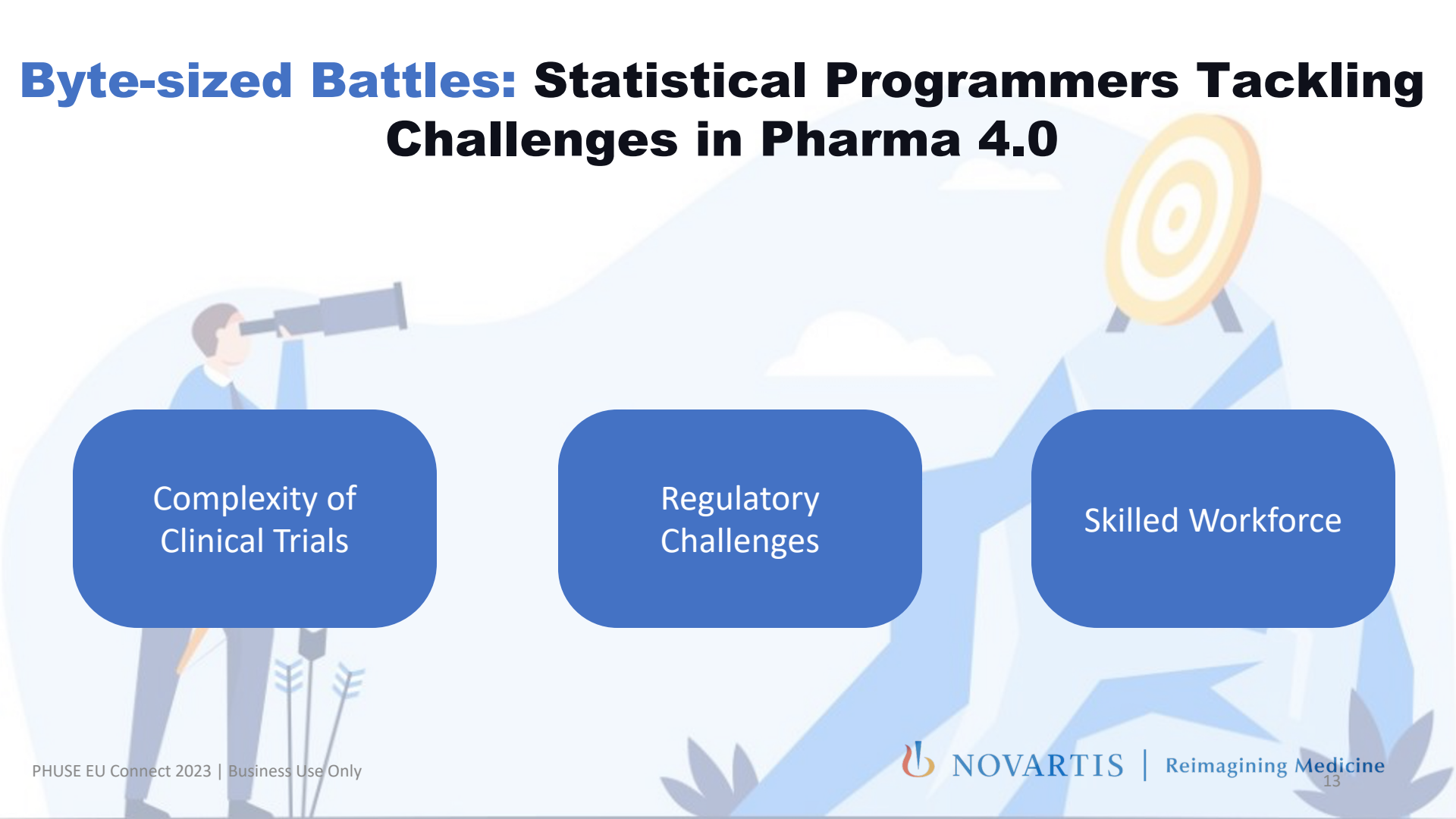
- The Breezhaler(TM) inhaler is the device for Novartis' portfolio of COPD treatments of Onbrez and Seebri, and Ultibro, the leading LABA/LAMA treatment
- The collaboration further supports Novartis' focus to empower patients making it easier for them to manage their own chronic disease by having near real time access to their own data on inhalation use
- Novartis plans to launch the next generation connected Breezhaler(TM) in 2019

Basel, January 5, 2016 - Novartis announced today a collaboration with Qualcomm Incorporated through its subsidiary, Qualcomm Life, Inc., in digital innovation with the Breezhaler(TM) inhaler device to treat COPD. Under this collaboration, Qualcomm Life will provide the technology solution for the connectivity of the next generation of the Breezhaler(TM) inhaler, a device used for Novartis' portfolio of COPD treatments of Onbrez(TM) Breezhaler Seebri(TM) Breezhaler, and Ultibro(TM) Breezhaler, the leading LABA/LAMA treatment.

Data lies at the heart of Pharma 4.0



Byte-sized Battles: Statistical Programmers Tackling Challenges in Pharma 4.0

The background of the slide features a stylized illustration. On the left, a person in a blue suit is looking through a large telescope. In the center, there are three blue rounded rectangular boxes containing text. On the right, a large yellow target with concentric circles is mounted on a blue structure. The entire scene is set against a light blue background with white clouds and stylized plants at the bottom.

Complexity of
Clinical Trials

Regulatory
Challenges

Skilled Workforce

Byte-sized Battles: Statistical Programmers Tackling Challenges in Pharma 4.0

Complexity of Clinical Trials

- Heterogenous Data
- Varying data formats & standards
- Remote monitoring
- Digital endpoints

Regulatory Challenges

- Interoperability and integration
- Varying regulatory expectations
- Transparency, documentation and response time

Skilled Workforce

- Rapid technological advancements
- Diverse skillset
- Time constraints

Redefining Possibilities: Solutions and Strategic Next Moves



Redefining Possibilities: Solutions and Strategic Next Moves

Understand End-to-End Data Lineage

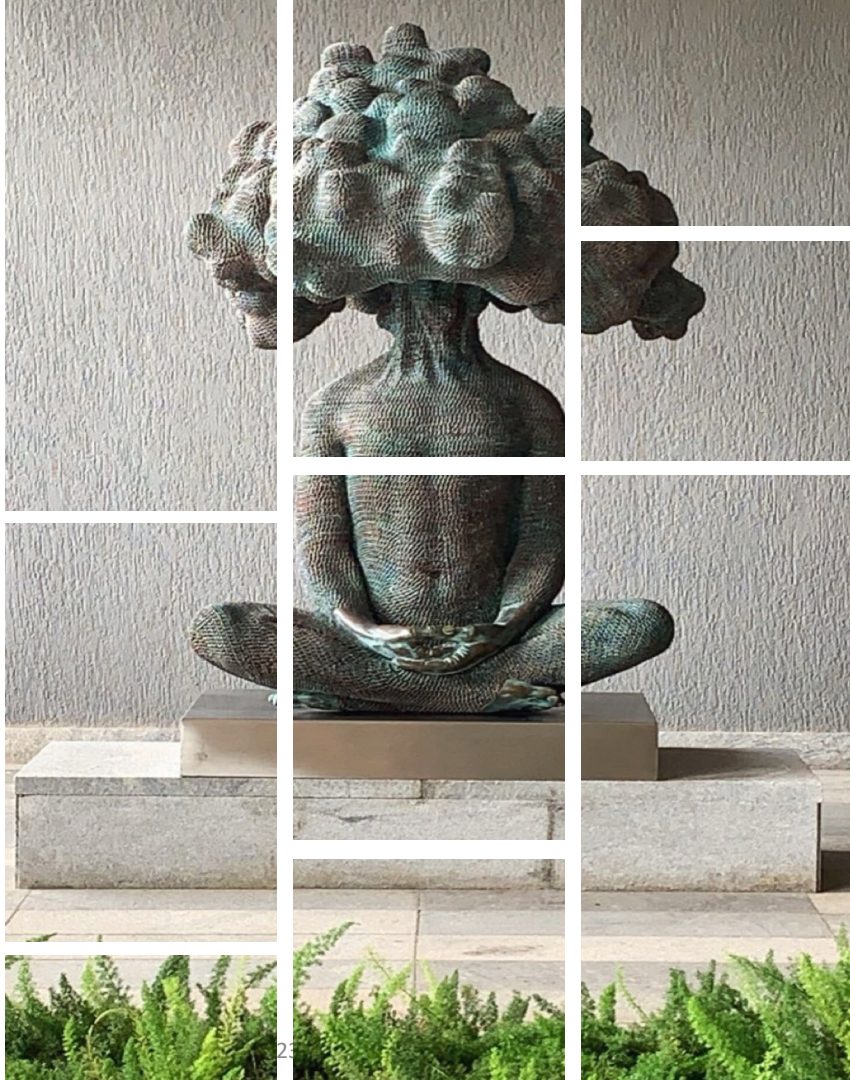
- Data source identification & integration
- Data transformation into analysis-ready datasets
- Analysis & Documentation

Standards and Stakeholders expectations

- Knowledge of regulatory guidelines
- SAP, analysis, deliverables rationale
- Statistician and clinician analysis POV

Upskilled and Agile teams

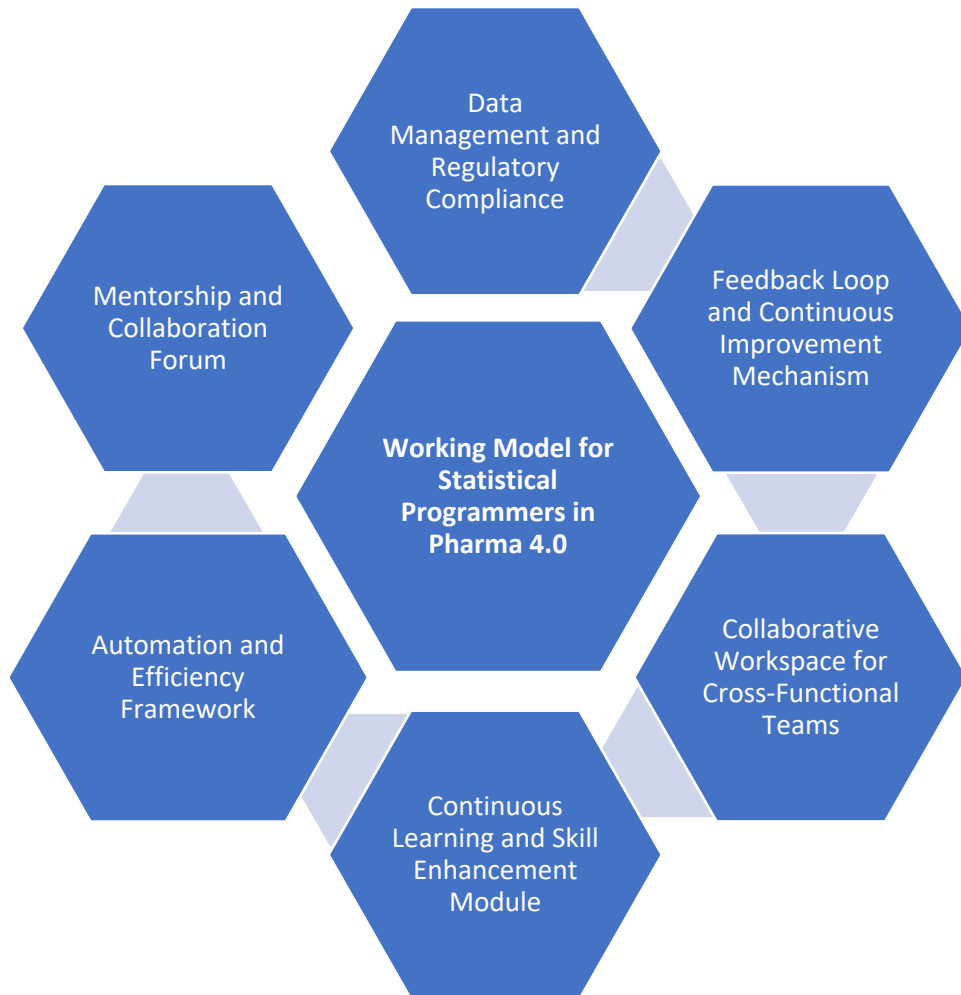
- Set Goals & prioritize learning & improvement
- Mentorship
- Growth mindset – apply agile methodology



The Evolution Blueprint: Crafting Solutions, Paving the Next Steps

Learning Model for Statistical Programmers in the Fourth Industrial Revolution





Working Model for Statistical Programming Function in the Fourth Industrial Revolution

CRISPR helps solve 100-year mystery of why cancer cells have extra chromosomes

Merck, Moderna Launch Pivotal Cancer Vaccine Trial for High-Risk Melanoma

psychedelic drug trials

Cosentyx Becomes First Biologic Approved For HS

BioSpace, July 26, 2023

Merck and Moderna announced Wednesday the initiation of a pivotal III high-risk melanoma trial combining the companies' mRNA-based personalized cancer vaccine with Merck's blockbuster Keytruda checkpoint inhibitor.

ChatGPT with pharma

data debuts

Explaining The Unexplainable: How To Win US FDA's Trust In Artificially Intelligent Drug Manufacturing

AI In Big Pharma:

Pink Sheet, August 7, 2023

The First Antibody Designed Using AI

We are not too far...

Connect Theme Presentations (SI)

CORE: Everything You Always Wanted to Know but Never Dared to Ask

Connect Theme Presentations (AD)

Innovative Applications of R Shiny in Clinical Research: Enhancing Efficiency, Collaboration and Data-Driven Decision-Making

Connect Theme Presentations (AD)

Transforming Statistical Computing Environments for Enhanced Efficiency in Clinical Trial Data Analysis: Innovations, Collaborations and Open Source Solutions

CM08: The Human in the Loop: Accelerating AI/ML Efficiencies for Clinical Data eClinical Solutions

Connect Theme Presentations (DS)

Digital Data Flow – From Vision to Reality

DS01: ICH M11 Clinical Electronic Structured Harmonized Protocol (CeSHarP) and CDISC: Making the Electronic Protocol a Reality
CDISC

DS02: The TransCelerate/CDISC Digital Data Flow Project: Practical Electronic Study Designs
data4knowledge

DS03: The Digital Protocol Is Just the Beginning. Or Is It?
Instem

SI07: Gear Up SDTM with Digital Health Devices
Novo Nordisk

Connect Theme Presentations (CM)

Unlocking the Potential of ChatGPT

CM04: Boosting SAS Programming Efficiency with ChatGPT: A Clinical Trial Perspective
Intego Clinical

CM05: GPT (Generative Pretrained Transformers) and LLM (Large Language Models) have generated a lot of attention since their inception in early 2023 with the advent of OpenAI GPT3.5, then GPT4.0
SAS & Microsoft

CM06: Unleashing the Power of Large Language Models for Clinical Data Approaches: Will AI Chatbots such as ChatGPT/Bard Replace Statistical Programmers and Statisticians Over Time?
Roche



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“You are a wizard, Harry”





Thank you!



Questions can spark great conversations.



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[Ritika Aggarwal](#)

References

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References

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 - [What is the fourth industrial revolution? | World Economic Forum \(weforum.org\)](#)