Implementation of statistical innovation in a pharmaceutical company

Kaspar Rufibach
Methods, Collaboration, and Outreach Group, Roche Basel
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Mouna Akacha (Novartis)

Co-authors of Rufibach et al. (2024)

Innovation = invention × commercialization.

Hurdles and how to overcome them.

Curiosity! And a few other things.

What is innovation?

Innovation is...
...invention times commercialization.

Bill Aulet

Professor of the Practice, Technological Innovation,
Entrepreneurship, and Strategic Management at MIT

Short youtube video

Invention: new method.

Commercialization: scaled-up implementation of invention.

Innovation = invention $\times$ commercialization.

Statistical innovations:

estimands

adaptR

rbmi

Successfully commercialized at Roche.

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Kaspar Rufibach[a], Marcel Wolbers[a], Jenny Devenport[b], Godwin Yung[c], Chris Harbron[d], Alun Bedding[d], Zhiyue Huang[e], Ray Lin[c], Herbert Pang[c], Daniel Sabanés Bové[f], and Jianmei Wang[d]

[a]Methods, Collaboration, and Outreach Group, Product Development Data Sciences (MCO), Hoffmann-La Roche Ltd, Basel, Switzerland; [b]Product Development Data Sciences, Hoffmann-La Roche, Basel, Switzerland; [c]MCO, Genentech, South San Francisco, California, US; [d]MCO, Hoffmann-La Roche Products Ltd, Welwyn, UK; [e]MCO, Hoffmann-La Roche, Shanghai, China; [f]Data Science Acceleration, Product Development Data Sciences, Hoffmann-La Roche Ltd, Basel Switzerland

ABSTRACT
Innovation, defined as the successful implementation at scale of a new invention, is key for continued success of the drug development enterprise. In this article we focus on statistical innovation in the pharmaceutical industry. We discuss both components, *invention* and implementation at scale, typically called *commercialization*, of innovation for statistical methods. These concepts are illustrated using three examples that we successfully implemented in our company. We summarize factors that foster or hinder invention and commercialization. A discussion of the mindset we consider supportive of innovation and how organizational leaders and professional organizations can generate an environment that fosters innovation concludes the article.

Rufibach et al. (2024)

Potential hurdles for commercialization

- **Insufficient knowledge**.
- **Lack of case studies**.
- **Lack of user friendly software**.
- **Regulatory position**.
- **Company-internal buy-in**.
- **Inertia**.
- **Statistician's mindset**.

  Yes, but have you thought about the assumptions, and this and that and blablablabla. Ah, and btw your proposal is great!

Paper: details & how to overcome hurdles.

Some success factors to innovate

- **Entrepreneurial spirit**:
  - Experts who are capable and can invest resources at their leisure.
  - Ownership, accountability.
  - Trust, reputation, credibility, network.

- **Organizational culture**: Accept failures without compromising on quality of work.

- **Specialized capabilities & investment**.

- **Software engineering**.

- **External collaboration**.

- **Designated project leadership**.

- **Timelines / urgency**.

- **Tools to facilitate adoption**.

- **Collaborations**:
  - Internally in other functions.
  - Industry, regulators, academics.

What statisticians do we need for innovation?

Curiosity!

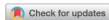# What statisticians do we need for innovation?

- Solid experience in drug development.
- **Invention**:
  - Broad methodological competence in statistics relevant to drug development.
  - Curiosity.
  - Park statistician's mindset of emphasizing everything that could go wrong.
  - Trust and credibility.
  - Collaborative: other methodologists, wherever they sit.
  - Remain connected to the drug development business.
- **Commercialization**:
  - Self-starter and pro-active.
  - Collaborative: Statistical engineering; statisticians working on projects; cross-functional molecule teams; senior management; regulators.
  - Persistence.
  - Modesty and teamwork. Sharing credit with collaborators who commercialize an invention is essential.

<div style="text-align:center">

Hire for both!

</div>

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Rufibach et al. (2024)

Thank you for your attention.

kaspar.rufibach@roche.com

Slides can be downloaded on
www.kasparrufibach.ch

References I

▶ Rufibach, K., Wolbers, M., Devenport, J., Yung, G., Harbron, C., Bedding, A., Huang, Z., Lin, R., Pang, H., Sabanés Bové, D. and Wang, J. (2024). Implementation of statistical innovation in a pharmaceutical company. *Statistics in Biopharmaceutical Research* .

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