

QUALIANCE

Therapeutic Area Knowledge: Beyond Connecting the Dots

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Disclosures

Former employee of

RetinaLyze · Novo Nordisk · Ferring Pharmaceuticals

Consulting services provided to

16 pharmaceutical, biotech and nutrition companies

Former service/technology partnerships

Two clinical-data service and software providers

Appointed expert member (pro bono)

EMA Technical Anonymisation Group (TAG) · Health Canada Public Release of Clinical Information (PRCI) stakeholder group

The views expressed are my own and do not represent those of any company or organisation I have worked with. **No company has reviewed or funded this presentation, and no confidential data is shown.** *AI tools were used in preparing this presentation.*

Better. Faster. Smarter.

AI is automating “better” and “faster”. “Smarter” is still our job.



The bridge runs both ways

With AI, our stakeholders can now do data science.

With AI, we can now learn their science.

AI gives both sides access. Only investment builds expertise.



We see the data first

CEO, regulator or statistician: every request passes through our hands first.

Gold is often passed on as soon as it passes validation.

Validated ≠ understood



Science is a contact sport

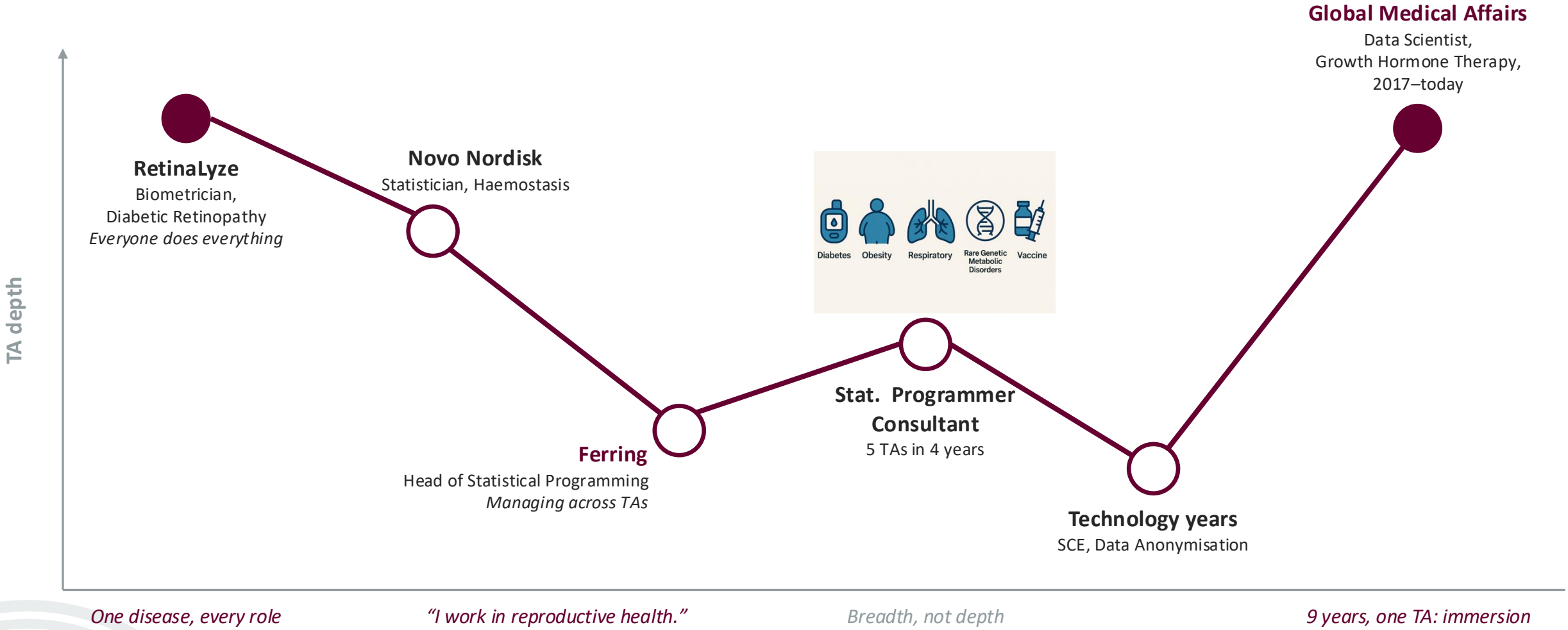
New signals are challenged. Opinions and interests collide.

This isn’t golf. It’s MMA: mixed disciplines, played by the rules.

Which disciplines are we training?

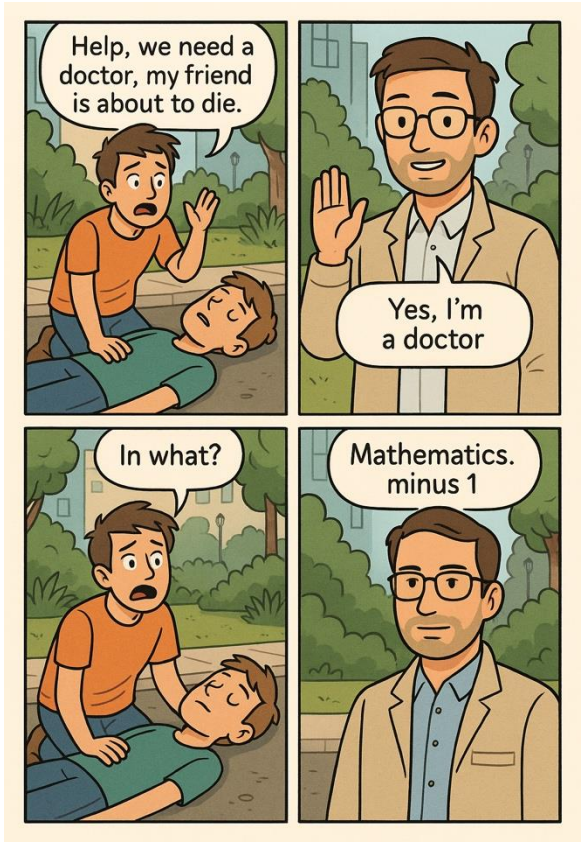
TA depth comes from focus

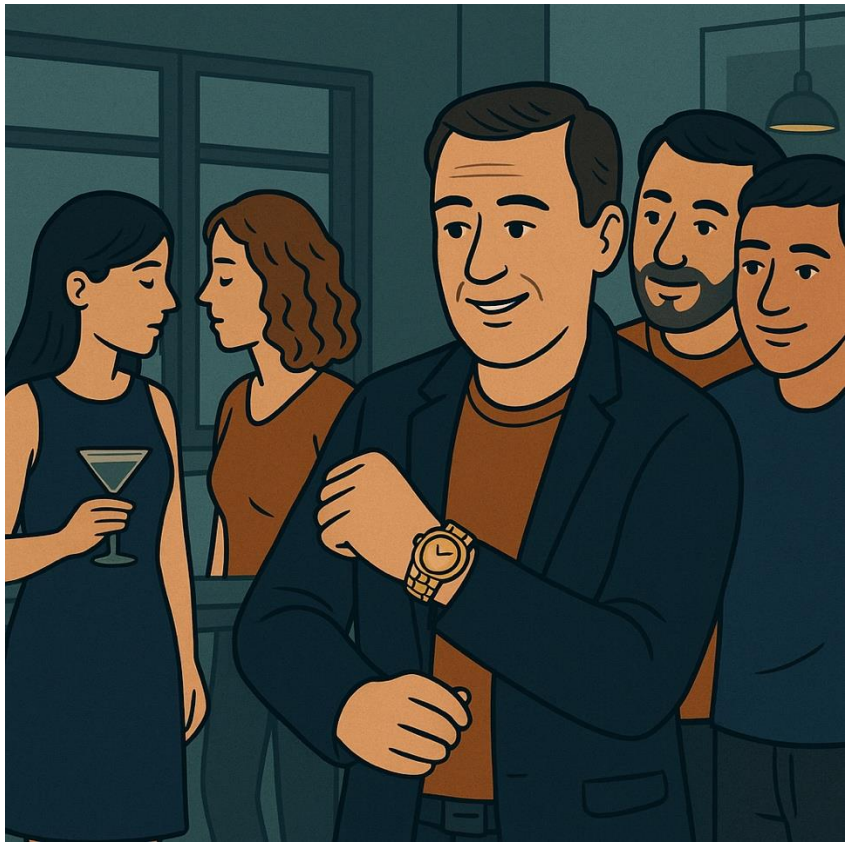
My journey, job by job



Therapeutic Area Knowledge

Get our priorities right…





Three layers of TA knowledge

At any point in time…

Less and less volume. More and more value for the data scientist.



What everyone agrees on

Learn it in our first months. AI shortens the learning curve — the entry ticket.

Where to find it
Textbooks · guidelines · review articles · AI



What everyone knows about, but disagrees on

Where the fights are. Our analyses become ammunition.

Where to find it
Congress panels · regional guideline differences · competitor trial designs



What nobody knows yet they'll disagree on

Often visible first in the data — in our hands. Only recognisable if we know the other two layers.

Where to find it
Congress posters · KOL Q&A · our own data

Five pillars of TA knowledge

The mixed disciplines

Disease & Patients

- Understand **the disease**: **axes and pathways**, natural history, **burden** and **quality of life**.
- Know the **state of diagnosis**: how and when patients are diagnosed, and **where they are missed** or diagnosed late.
- Understand **today's treatment burden** for patients and caregivers.
- Connect the **patient journey** to **which data matter** (long-term follow-up vs short trials).

Therapies & Clinical Practice

- Know which **endpoints clinicians trust** and why (objective vs subjective, surrogate vs hard outcomes).
- Integrate **regional guideline differences** in treatment, dosing and outcomes.
- Recognise **bias and confounding** in treatment choices.
- Identify **gaps** where real-world data could complement clinical trials.

Stakeholders & Influencers

- Understand what **KOLs, HCPs, payers and affiliates** consider clinically relevant, and where they see the greatest **unmet need**.
- Know **where the field disagrees**: the debated questions, and who stands where.
- Translate statistical outputs into the **language of clinicians and patients**.
- Anticipate the **questions regulators and payers** will raise about **evidence robustness**.

Competition & Market Dynamics

- Compare **what data competitors have vs. what we have** (long-term safety, real-world adherence, rare subgroups).
- Spot **data asymmetries**: places where we can generate evidence to differentiate.
- **Analyse trial designs**: what endpoints they choose, what populations they target.
- Anticipate how data could be used in **competitive positioning**.

Medical Affairs Angle

- Suggest **follow-up analyses, registries, or studies** that could strengthen medical evidence.
- Translate complex analyses **into clinically meaningful narratives** for Medical Affairs materials.
- Partner to **shape study design questions**, not just deliver statistical results.

Building TA expertise in practice

From mindset to habits

📖 Following the science

- **Key journals** and **landmark papers** in our TA; alerts are more targeted than social feeds.
- **Sharing what we read with medical colleagues** often starts the best conversations.

🧠 Using AI as a tutor

- **Summarising articles**, **comparing endpoints**, **mapping competing trials** across the five pillars.
- **Explaining mechanisms of action** in plain language and linking biology to endpoints and subgroups.
- **Rehearsing before medical meetings**: AI plays the clinician and challenges our reading of a finding — *within approved tools*.

💡 Shaping the questions, not only the answers

- Analysis plans answer questions someone else has framed.
- **With TA knowledge, we can help frame them**: propose analyses, spot evidence gaps, note where studies fall short.

🎤 Going where the science happens

- **Medical congresses**, even virtually.
- The questions KOLs get from their peers reveal **disagreements and research gaps**: the debated and emerging layers.

🗣️ Speaking our stakeholders' language

- Clinicians think in **axes and pathways**, and in "clinically meaningful", "quality of life", "unmet need". P-values are only part of the story.
- Their language **builds trust** and helps our work reach beyond the data science community.

📜 Earning scientific credibility

- Authorship follows contribution: **co-designing analyses**, suggesting endpoints, interpreting findings.
- **Peer reviewing** keeps us current and builds a scientific footprint.

Improve your signal-to-noise ratio

LinkedIn for people. ResearchGate for science.

Great for
Who moved where, who's hiring, event news

Costly for science
Self-promotion, certificates, engagement bait.
A lot of scrolling for one relevant post.

Your research in one place
Journal papers — plus your PHUSE papers and posters. No publications yet? Following is where the value is.

Notifications that matter
When your work is cited, when co-authors publish, when people you follow add new research.

Free
The free account is all you need.

Do it this week

1. Create a free profile, confirm the publications it suggests
2. Add your PHUSE papers and posters
3. Follow 10 researchers and 3 topics in your TA
4. Switch on citation and co-author alerts
5. **Book 30 minutes a week to read your notifications**

Conclusions

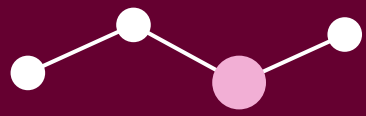
1. **The bridge runs both ways**
   AI gives us access to our stakeholders' science. Building depth is still up to us.

2. **Validated is not understood**
   We see the data first. The value lies in noticing what it means.

3. **TA depth takes mixed disciplines**
   Disease, therapies, stakeholders, Medical Affairs, competition.

4. **TA depth is a second kind of expertise**
   Titles track technical expertise. TA depth grows with time spent in one area.

5. **A small experiment**
   Next time we meet a new team, let's try naming our therapeutic area before our job title.



Connecting the dots is the job.

Knowing which dots matter is the expertise.

THANK YOU!

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