Beyond the hype: Tackling AI fears and wins in RA

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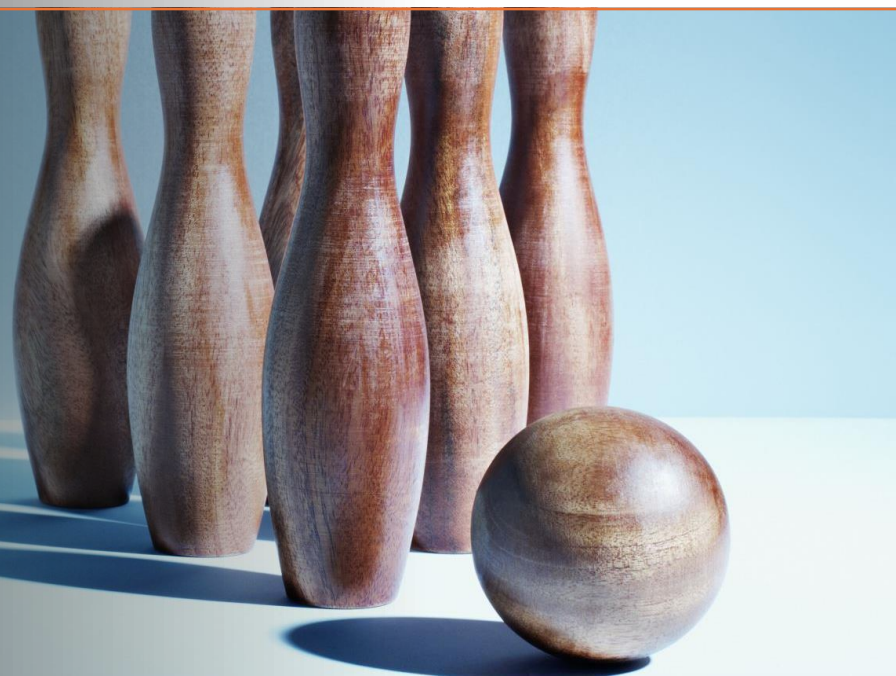

What are we talking about?

- This is not hype
- Why AI and why now?
- How it makes me feel?
- What is really possible for me?
- What are the rules of the game?
- Where do we start?
- Q&A

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This is not hype

When you hear the phrase “AI in regulatory affairs”, what is your immediate gut reaction?

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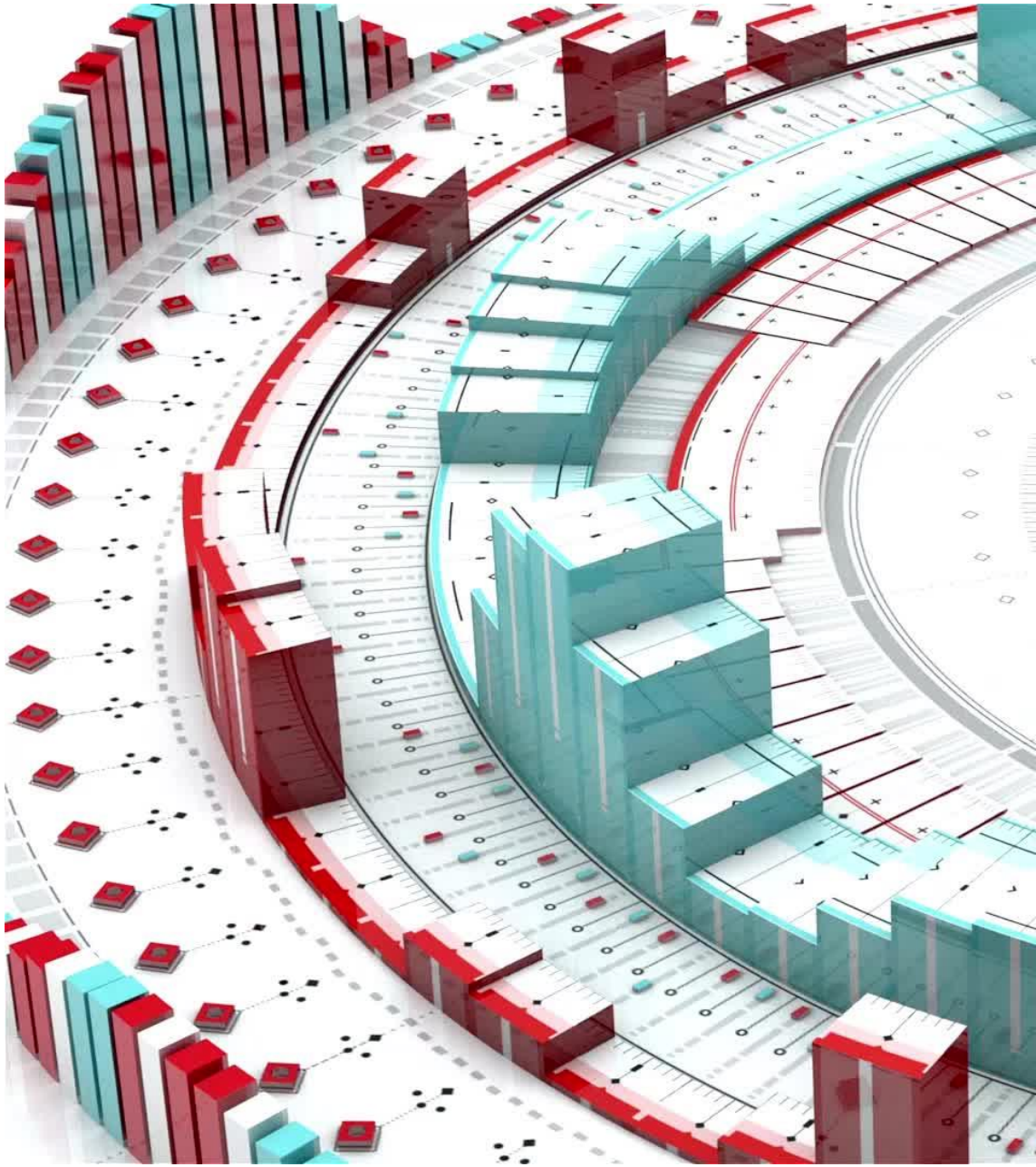
This is not hype. This is here.

Imagine a future where:

- **AI co-pilots are going native**
  - Built directly into your RIM, PV, QA, and LCM platforms
  - 80% of global life sciences companies plan AI integrations in their regulatory systems by 2026 - McKinsey, 2024.
- **A new role is emerging: the AI-QP**
  - A governance lead managing prompt logs, output validations, and audit readiness - EU AI Act.
- **At least 30% of routine regulatory tasks will be automated, much more expected**
  - Dossier compilation, labelling updates, SOP drafting, signal screening, lifecycle submissions – all AI supported - Accenture Intelligent Life Sciences, 2024.
- **Workflows are becoming multilingual, connected & agent-driven**
  - AI interpreters, regulatory chatbots, smart SOP assistants — ready to scale and adapt across geographies - IQVIA.



This is changing the game – and your role

AI isn't replacing Regulatory Affairs. But it is changing what RA means

- We are entering a new era — one where **AI becomes the invisible layer beneath your work**. It supports, accelerates, and transforms.
- But here's the truth: your **job is already changing.**

  - **75%** of big pharma companies are piloting or deploying **generative AI for SOPs, labelling, and submissions – McKinsey, 2024**
  - **43%** of global life sciences companies are already using AI in **regulatory or safety functions –** Accenture, 2024
  - **30–40%** of manual PV and literature tasks can already be automated with validated AI tools - Deloitte, IQVIA Use Cases
  - **80%** of regulatory professionals expect **AI to change their role** by 2027 - Gartner Life Sciences Trends, 2024
  - **95%** of AI-generated regulatory outputs still require **human review, judgment, and traceability**

Why AI and why now?

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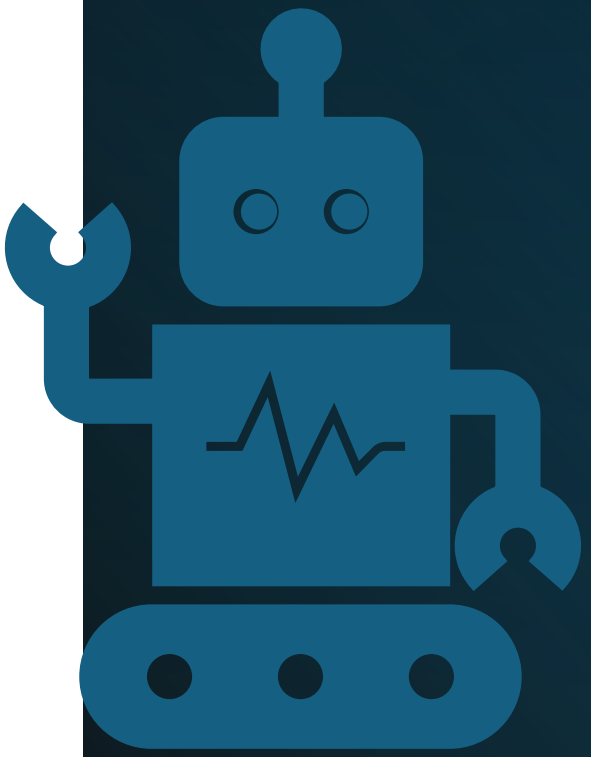
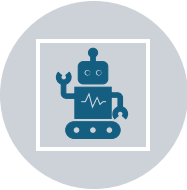
Why AI and why now? What forces are driving change in regulatory affairs?

- Perceptions on major changes…



Why AI and why now? What is driving change in pharma, regulation and healthcare?



Technological acceleration - AI, digital health

Economic inequality - Shifting income groups, LMIC pressure

Political Nationalism - Localisation, trade barriers

Decentralised trials - Patient-centric, remote data capture

Consumerisation & misinformation - Trust, social media

Demographic & workforce shifts - Migration, urbanisation, ageing

Why AI and why now? What makes it so different?

- It’s Adaptive, Not Just Functional
- It Automates *Thinking*
- It’s General-Purpose and Cross-Industry
- It Replicates (and Amplifies) Human Capabilities
- It Moves *Faster Than Regulation or Comprehension*

AI isn’t just a tool or a platform—it’s an intelligent layer capable of **transforming how we think, work, and create**. It’s not the next internet, it’s the next **intelligence**

What makes it so different?

Then: The Energy revolution

Before electricity,

energy was localized and manual—firewood, watermills, steam.

Every...

household, workshop, or factory had to **generate and manage its own power**.

With the rise of...

centralized electricity grids, energy became **scalable, reliable, and widely accessible**.

Enabling...

industry, cities, automation, and our entire digital world.

Then: The intelligence revolution

Before AI...

cognition—problem solving, interpreting data, making decisions—was **human-only and local**.

Every...

Organization had to build its own logic, rules, training, and decision models **manually**.

With the rise of...

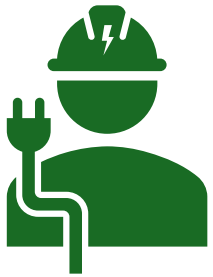
general AI platforms and models utility—scalable, on-demand, and context-adaptable

Enabling...

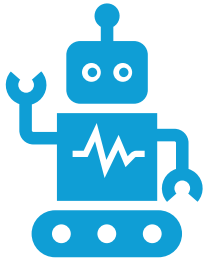
automated insights, human-machine collaboration

Why AI and why now?
What makes it so different?

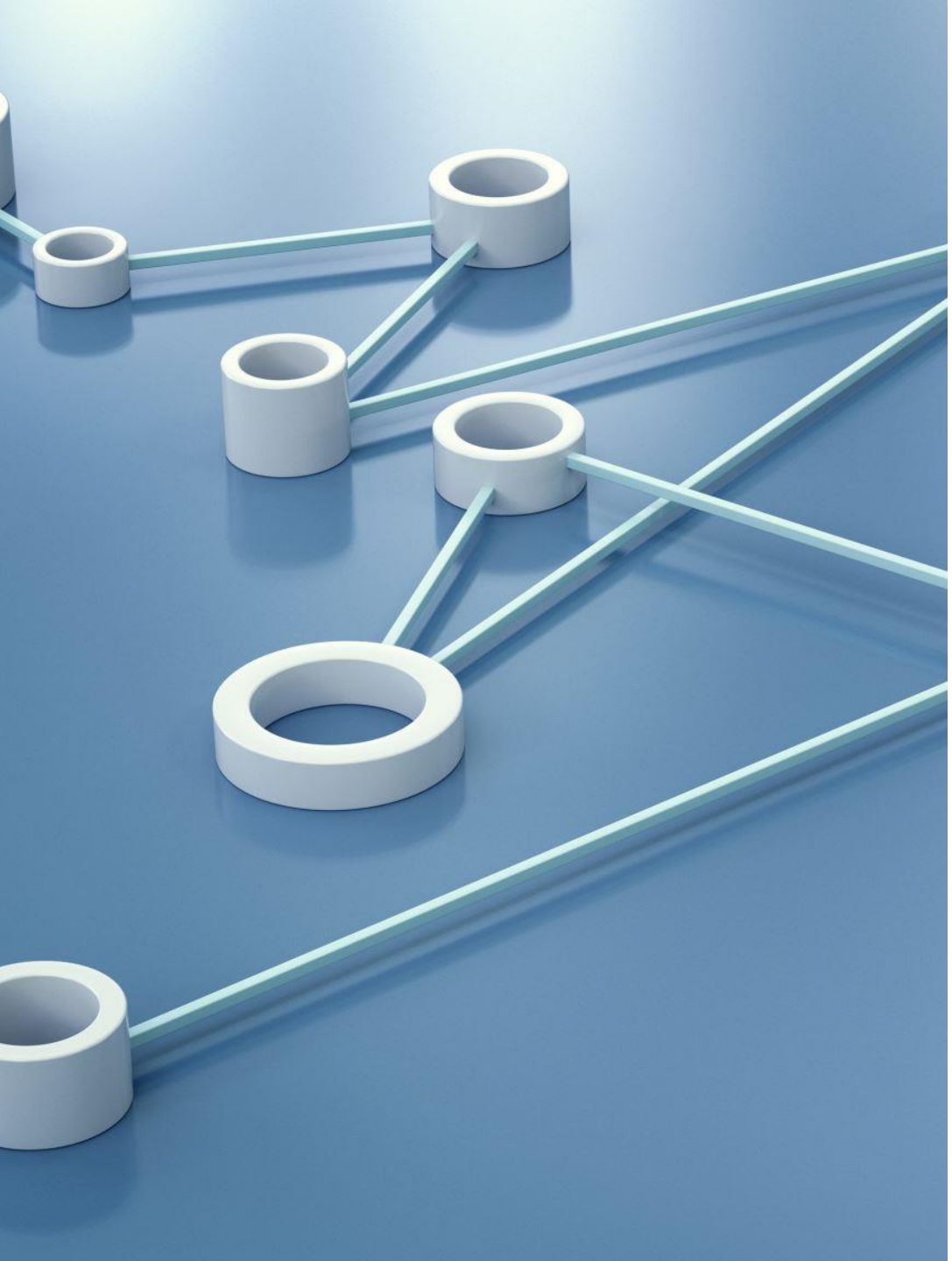
Like Electricity Transformed Energy, AI Transforms Thought



Electricity became the general-purpose infrastructure for *doing things*. Electricity automated physical work



AI is becoming the general-purpose infrastructure for *thinking and deciding*. AI automates mental work.



Why AI and why now? Impacts on the regulatory value chain

1. From Static Dossiers to Living Submissions

- Real-time, modular regulatory submissions.

2. Rise of Multi-Speed Regulatory Strategy

- Flexible, tiered strategies for diverse requirements

3. Expanded Scope of Regulatory Intelligence

- Real-time monitoring and actionable insights

4. Regulators as Perception Managers, Not Just Gatekeepers

- Anticipate reputational risks and communicate science.

5. Strained Human Infrastructure Demands Tech-Augmented Capacity

- Automation and AI powered workflows

Why AI and why now? Global trends

1. The Rise of Adaptive Licensing & Modular Submissions (EU, US, Global)

- *Trend:* Regulators like EMA and FDA are embracing **rolling submissions**, **adaptive pathways**, and **real-time evidence integration**.
- *Why It Matters in LMICs:* These innovations set the bar for **regulatory harmonization** and **tiered access models**—paving the way for **faster African approvals** if local authorities can plug into modular, shared data models.

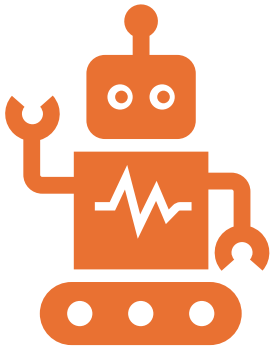
2. The Localization vs. Globalization Tug-of-War (India, US, EU, Africa)

- *Trend:* Countries are **tightening local manufacturing policies**—India's PLI schemes, EU's critical medicines strategy, and Africa's local production push.
- *Why It Matters:* Any company going cross-border must **build regulatory strategies that fit national pride**—and **prove local value creation**, not just clinical benefit.

3. The Professionalization of Regulatory Intelligence and Public Trust (US, Brazil, Africa)

- *Trend:* Regulatory teams are becoming **crisis communicators, real-time analysts**, and **policy influencers**.
- *Why It Matters:* RA professionals are no longer "paper pushers." They're now **navigators of science, politics, and public perception**—and increasingly require **tech tools to manage this complexity**.

How does it make you feel?



Do you ever feel you're "falling behind" in understanding AI compared to others?

How do you currently feel about the impact of AI on your job security or future role in regulatory affairs?

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How it makes you feel
The knowledge of scale

Average Regulatory Professional

- ~100,000 pages of knowledge
- Built over 10–15 years
- SOPs, guidelines, product experience, legislation
- Deep context, intuition, risk interpretation
- Narrow but nuanced

You know the environment. You understand consequence.

AI (typical LLM model)

Trained on:

- **1 million books**
- Full **Wikipedia**
- Global **medical & regulatory literature**
- Public scientific papers
- **Code repositories**
- **Hundreds of billions of words**
- Estimates: *Equivalent to reading nearly every document on the public internet*

A million lifetimes of learning compressed into probabilistic prediction.

What’s really possible for me?

What is really possible for me?

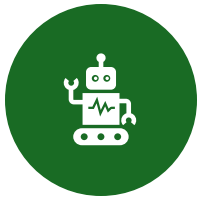
DON’T GET OVERWHELMED WITH THE OPTIONS BUT KEEP TRUSTED INTEGRATORS CLOSE

DON’T ATTEMPT MAJOR CHANGES WITHOUT SOME CHANGE MANAGEMENT

THINK NON-REGULATORY TO BEGIN WITH, GENERAL PROBLEMS TO SOLVE

What is really possible for me? How it should help you

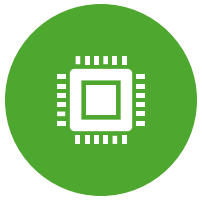
The Pathfinder – Customer Journey Optimiser - “If your customer ever feels lost… I’ve failed.”



The Mirror – Market Intelligence Analyst - “Your customer sneezed and your competitor blinked. I noticed both.”

The Automator – The Unseen Assistant – “I’m not here to **take your jobs, just your drudgery**.”

Data Surge – The Relentless Ocean - “I’m here to **turn oceans of data into waves that can be surfed.”**



The Hybrid Phantom – The Workplace Shapeshifter - "Work is a **state of mind, not a location**."

The Knowledge Navigator – The Librarian of the Future - “True mastery isn’t in memorization, but in knowing where to look.”

The Re-Skiller – The Relentless Mentor - “A tireless, restless teacher who never stops moving”.

What are the rules of the game?

The rules of the game

Key Shortcomings of LLMs in the Regulatory Context

- **Confident but wrong:** LLMs generate content that *sounds right* but can be inaccurate or legally risky.
- **Positivity bias / syncopath:** LLMs tend to smooth over complexity or risk, lacking critical nuance.
- **Fuzzy grey areas:** There's no "source of truth" — just predictions based on patterns in training data.
- **Limited transparency:** Some LLMs struggle to explain how or why they gave an answer.
- **Inconsistent outputs:** The same prompt can yield different responses at different times.

How LLMs work – and why it matters for safety
Understanding the tech helps you ask the right questions.

Training & Knowledge Base

- LLMs are trained on **massive datasets** (books, websites, code, articles).
- They **predict the next word**, not "look up" a fact.
- Public versions may **use your inputs** to train the model.

Just because you can ask AI anything doesn't mean you should

Ask These Questions When Using AI Tools:

1. **Does it store or use my data?**
    - Use enterprise or private versions with *data retention OFF*
2. **Do I need this tool for a GxP environment? If yes, then:**
    1. **Is this tool validated for GxP environments?**
    - Log all prompts and outputs, apply human review, and assess risk (GAMP 5).
    2. **Is this output verifiable?**
    - Cross-check citations, confirm against official HA guidance (FDA, EMA, SAHPRA).
3. **Can this expose confidential IP or patient data?**
    - Mask identifiers, redact sensitive terms, and work only in secured tools.

RA safety checklist
What regulators, clients, and best practice already require for AI use in regulated environments

✔ Do	✖ Don't
Use AI tools with zero data retention (the data rules still apply)	Share confidential data in public/free AI tools
Log every prompt/output in GxP-relevant workflows	Assume AI content is submission-ready or regionally compliant
Keep a human-in-the-loop on all AI-generated outputs	Use AI for legal interpretation or PV report finalisation
Mask or redact product, MAH, or patient identifiers (anonymise, minimise, secure)	Use AI to process regulatory or HA correspondence without review
Validate against official sources	Trust public LLMs for high-risk, safety-critical tasks
Apply risk-based validation to AI tools (GAMP5, FDA GMLP, GDPR)	Use AI tools that lack audit trails or transparency

Where do we start?

Where do we start?

- Play around with basic tools (as per slide above)
  - Prompt engineering basics
  - Business use case and integration tools

Where do we start? Practical ways of how it can help you

Quick guide on how to think about making it practical…

- Inferential computing: Think like a human, not a workflow
- Manual to technological: Don’t impose manual ways on an AI solution
- Multiple perspectives: Frame the service or solution according to multiple stakeholders’ perspectives – involve your own organisation!
- Service orientation before just operational efficiency: What will create value in future

Prompt engineering basics

Be Specific with Context

- "Garbage in, garbage out" applies here too.
- **DO**: Provide relevant **regulatory context**: e.g., "For a generic product registration in Kenya…"
- **DON'T**: Just ask "How do I register a product?"
- **Example**: DO: "Summarize section X for a BTIF for a solid oral generic being registered in Nigeria." DON'T: "Summarize this document."

State the Output Format

- AI performs better when you say *how* you want the result.
- Ask for **tables, bullets, summaries, decision trees**, etc. Specify file formats if needed (e.g., Excel structure, Word format).
- **Example**: "Turn this product data into a 5-column table with dosage form, strength, pack size, MA holder, and country."
- DON'T: "Organize this data."

Roleplay the Model

- Tell your tool *who it is* to help it respond with the right lens.
- Phrase like: "You are a regulatory affairs manager specializing in African markets…"
- **Example**: "You are a pharmacist working on eCTD submissions in SADC countries. Help me create an application letter for product X."

Prompt engineering basics

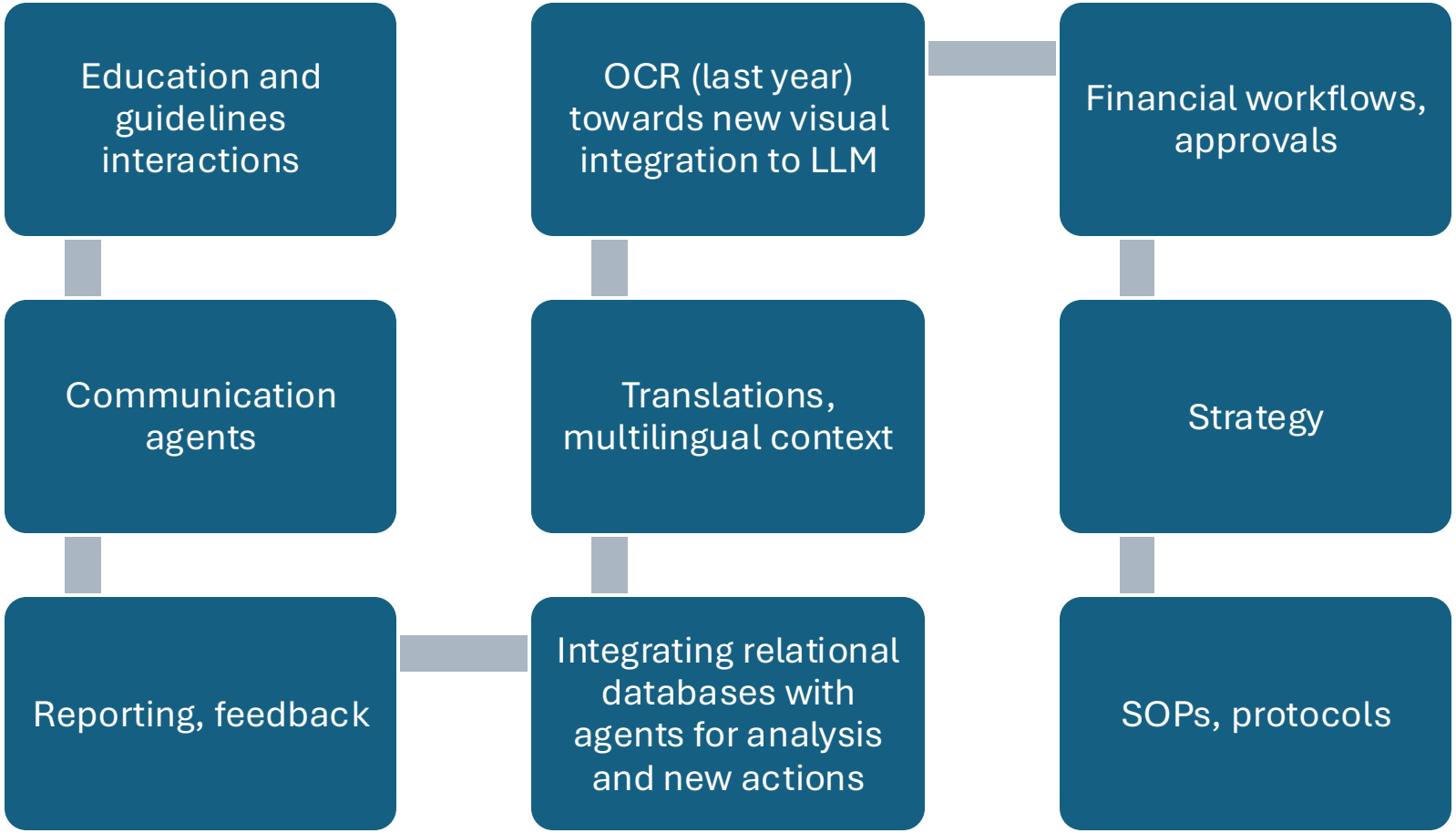
Break Big Questions Into Smaller Parts

- AI handles **sequential tasks** better than vague, complex ones.
- Start with: “Summarize these 3 documents.”
- Then ask: “What gaps do you foresee against SAHPRA Module 1?”
- **Pro tip**: Use *follow-up questions* rather than cramming it all in one go.

Iterate and Refine Like a Regulator

- Like reviewing a dossier — prompt, evaluate, tweak.
- Use terms like “Improve this,” “Make it more formal,” or “Add country-specific notes.”
- Don’t hesitate to say: “Now do it again, but shorter/more technical/more visual.”
- **Example**: “That’s good, now reword it to suit a slide for a senior regulatory manager.”

Where do we start? Practical ways of how it can help you



Where do we start?

Safety guidelines and measures (from previous slide)

Business case, practical need

Agree human in the loop review points

Pick a pilot and build

Draft internal AI usage SOP

Track ROI, benefits

Expand to other cases

Q&A

Open floor

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