5th Club

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Medical Affairs Club

The Launch Curve: From Science to Commercial Success

Online zoom
7 pm Egy - 8 pm KSA - 8pm UAE

Dr. Samer Ahmed
Head of Global Commercial New Products, Dr Falk Pharma, Freiburg, Germany

Wednesday 20th Aug 2025

Who is the speaker?

Personal Information

- Name: Samer Ahmed
- Age : 39
- Languages: English, German, Arabic

Education:

- MBA, in International Business Consulting.
  - Offenburg- University of Applied Sciences, Baden-Württemberg, Germany
- Bachelor of Pharmaceutical Sciences and Drug Design.
  - Ain Shams University, Egypt

Who is the speaker?

Educational Background

- Bachelor of Pharmaceutical Science
- Master of International Business Consulting

Global Experience

- Sales & Training
- Local, Regional and Global marketing
- Global Launch and portfolio management
- Global Innovation
- Global Commercial New Products

Industry Knowledge

- More than 15 years in the industry
- Experience with more than 75 countries worldwide.

Diverse Portfolio

- RX, OTC, FS and Medical devices.
- Different therapeutic areas
- Different business models in multinational organizations

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MERCK

SERVIER

MERCK

Nestlé

Boehringer Ingelheim

-Heel Healthcare designed by nature

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DrFalk

The Launch Paradox

- Top 10 launches often drive >50% of total growth in Big Pharma portfolios. These are typically blockbusters or first-in-class therapies with high strategic priority.

- Successful launches require:
  - Speed 🚀 – Rapid time-to-market and uptake
  - Access 🔓 – Reimbursement, formulary inclusion, affordability
  - Education 🎓 – HCP awareness, patient literacy, advocacy

- Underperformance Risk
  - 50–80% of launches underperform vs. forecasts:
  - 66% fall short in year
  - 78% continue to underperform in year 2
  - 70% still lag in year 3

Vision drives new products strategy

Model Type	Key Traits
Innovators	High risk, high reward, patents
Generics	Rapid entry, affordability, scale
Specialists	Niche markets, premium pricing
OTC/Nutraceuticals	Consumer-driven, lower barrier
Hybrid	Balanced portfolio for resilience

Global vs Regional Strategy

- Developed Markets (US, EU, Japan):
  - Reward true innovation and strong IP
  - Success driven by patented new drug approvals and large-scale launches
- Emerging Markets (Asia, LATAM, MENA):
  - Reward speed, adaptation, and affordability
  - Success often involves:
    - Line extensions
    - Local branding
    - Fast registration of smaller products
- Strategic Adaptation:
  - Example: A multinational may launch a complex biologic in the US/EU, but focus on branded generics or reformulations in Asia or LATAM

Key Message:
Align product strategy with **regional market expectations** while staying true to the **global company vision**

Scouting for New Products – Active vs. Passive

🔍 Active Scouting

- Proactive, goal-driven search for specific assets
- Tactics: Partnering conferences, outreach, database screening
- Example: Seeking gene therapy startups for rare diseases
- Requires clear strategic vision and dedicated resources

🌐 Passive Scouting

- Open-ended, exploratory approach
- Tactics: Innovation portals, crowdsourcing, academic networks
- Focus on serendipity and broad idea capture
- Encourages unsolicited proposals and unexpected innovation

⚖️ Balanced Approach

- Leading companies combine both:
  - Actively pursue strategic priorities
  - Passively scan for disruptive ideas

Ensures a rich pipeline of both targeted and emergent opportunities

Key Players in Scouting

- Business Development & Licensing

- Lead scouting and deal-making
- Use databases, tech platforms, and industry intelligence
- Attend partnering conferences (e.g., BIO, J.P. Morgan)
- Evaluate scientific merit and commercial potential
- Actively manage portfolios: in-license aligned assets, out-license non-core ones

- Search & Evaluation Teams

- Specialized in identifying external innovation
- Screen assets for strategic fit
- Maintain networks with academia, startups, and incubator

Internal Inputs – Field Teams as Innovation Scouts

- Medical Sales Representatives

- Gather market insights from HCPs
- Identify unmet needs, off-label uses, competitor buzz
- Provide bottom-up signals for product development

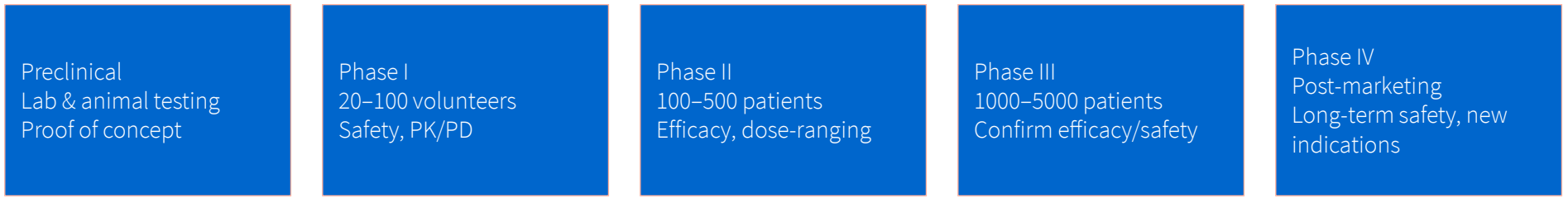
- Medical Affairs Managers & MSLs

- Engage with KOLs, researchers, and attend conferences
- Spot emerging science and clinical trends
- Inform trial design and label expansion opportunities
- Ensure clinical relevance in development programs

- Feedback Loops

- Insights shared via reports, meetings, innovation portals
- Field teams treated as strategic contributors
- Continuous frontline feedback improves launch success

Clinical Development – From Science to Commercial Success



🔬 Phased Trials & Evidence Generation

- Phase I–III trials assess safety, efficacy, and value
- Only a small % of compounds reach approval
- Output: Regulatory dossier (NDA/BLA) for FDA/EMA

📈 Strategic Clinical Planning

- Align trials with product positioning and market access
- Include endpoints that matter to regulators, payers, and prescribers
- Design for differentiation (e.g., head-to-head trials)
- Plan globally for multinational approvals

From Clinical to Commercial Readiness

🤝 Cross-Functional Collaboration

- Input from Medical Affairs, Commercial, Market Access
- Ensure trials generate launch-ready evidence
- Medical Affairs now a strategic partner in early development

✅ Regulatory Milestone

- Approval enables launch, but doesn’t guarantee success
- Launch readiness often begins during regulatory review

📊 Post-Approval Studies

- Phase IV trials support safety, marketing, and lifecycle growth
- Real-world data and new indications extend product relevance

Pre-launch preparation: Strategic Positioning & Market Insight

📣 Product Positioning & Differentiation

- Craft clear, compelling messaging: efficacy, safety, convenience, cost
- Use clinical data + value-added services (e.g., patient support, diagnostics)
- Example: Xarelto's success via "once-daily" simplicity

🔍 Market Research & Insight Gathering

- Survey HCPs, patients, payers to refine messaging
- Translate insights into actionable strategies
- Address real-world barriers (e.g., injection fear, monitoring burden)

Pre-launch preparation: Scientific Engagement & Market Access

👨‍⚕️ KOL Engagement & Medical Education

- Advisory boards, congress presentations, disease awareness
- Build scientific credibility pre-launch
- Prepare medical info teams for HCP inquiries

💰 Market Access & Pricing Strategy

- Conduct HEOR studies (e.g., QALY, budget impact)
- Engage HTA bodies early (e.g., NICE)
- Use tiered pricing, access programs to remove barriers
- Align pricing with regional affordability and volume goals

Pre-launch preparation: Operational Readiness & Launch Execution

🚚 Regulatory & Logistics Readiness

- Build inventory pre-approval (at financial risk)
- Prepare compliant promotional materials
- Simulate launch readiness across cross-functional teams

🧠 Launch Execution Planning

- Align sales force, distribution, and medical teams
- Ensure physicians are primed via scientific buzz
- Launch readiness workshops to catch gaps

Medical Affairs – Scientific Leadership in Launch

📚 Scientific Credibility & Education

- Educates HCPs on clinical data, usage, and treatment positioning
- Provides balanced, evidence-based information
- Builds trust, especially for novel or first-in-class therapies

👨‍⚕️ KOL Engagement

- Develops relationships with key opinion leaders
- Facilitates advisory boards, symposia, and publications
- Ethical, transparent advocacy accelerates adoption

📊 Evidence Generation & Communication

- Supports post-marketing studies, registries, real-world data
- Translates complex findings into clinical insights
- Reinforces product value beyond initial trials

Medical Affairs – Compliance, Ecosystem & Feedback

✅ Regulatory & Ethical Compliance

- Ensures promotional activities stay within legal bounds
- Handles off-label inquiries per compliance rules
- Protects company reputation and launch integrity

🌐 Stakeholder Engagement

- Engages patient groups, pharmacists, guideline committees
- Promotes disease awareness and inclusion in treatment guidelines
- Builds a supportive ecosystem for product uptake

🔁 Feedback to Internal Teams

- Shares post-launch insights with R&D and marketing
- Identifies new opportunities, unmet needs, and optimization paths
- Drives continuous learning and lifecycle relevance

Sales Force – Driving Launch Uptake

📣 Awareness & Adoption

- Reps introduce the product post-approval
- Deliver digestible, relevant clinical info to busy physicians
- Reinforce core messages and encourage trial use

🤝 Relationship Building

- Build trust through personalized service
- Provide samples, brochures, and connect HCPs to MSLs
- Human engagement remains key, especially for complex therapies

📍 Reach & Coverage

- Strategic deployment by region and specialty
- Under-investment in reps = missed prescribers
- Use CSOs or expand teams to blitz the market during launch

Sales Force – Training, Support & Feedback

🎓 Training & Expertise

- Intensive pre-launch training on product, trials, competitors
- Equip reps with FAQs, objection-handling guides
- Help physicians map therapy to patient needs

💼 Customer Experience

- Support offices with reimbursement, starter kits, education
- Positive rep interactions drive brand preference
- Aim for high Net Promoter Score (NPS) among physicians

🔁 Feedback & Agility

- Reps relay real-time insights from the field
- Inform strategy tweaks, messaging updates, and targeting shifts
- Treat launch as a “micro-battle” with frontline adaptation

Case Studies

- Harvoni (Gilead Sciences) – Hepatitis C
  - Launch Year: 2014
  - Peak Sales: $10.67 billion
  - Narrative: Harvoni transformed Hepatitis C treatment with a once-daily, interferon-free regimen that cured most patients.
  - Strategic Insight: Gilead balanced a high price with strong payer strategy and aggressive KOL engagement.
  - Outcome: Rapid uptake and record-breaking sales.
  - Key Lesson: A curative therapy with a simple regimen and strong stakeholder alignment can overcome pricing barriers.

- Lipitor (Pfizer) – Cholesterol
  - Launch Year: 1997
  - First-Year Sales: $1.54 billion (inflation-adjusted)
  - Narrative: Lipitor entered a crowded statin market and quickly rose to dominance due to superior efficacy.
  - Strategic Insight: Massive sales force deployment and broad prescriber targeting.
  - Outcome: Became the best-selling drug of all time.
  - Key Lesson: Scale and superior data can drive mass-market success.

Case Studies

- Revlimid (Celgene) – Multiple Myeloma
  - Launch Year: 2006
  - Peak Sales: $12.1 billion (2021)
  - Narrative: Revlimid launched for relapsed myeloma and evolved through continuous evidence generation.
  - Strategic Insight: Extensive Phase IV trials and lifecycle management kept it relevant.
  - Outcome: Over a decade of dominance in hematology.
  - Key Lesson: Post-launch innovation sustains long-term commercial success

- Xarelto (Bayer/J&J) – Anticoagulation
  - Launch Year: 2011
  - Peak Sales: $6.5 billion (combined global)
  - Narrative: Xarelto wasn't first, but it was simpler—once-daily dosing and no blood monitoring.
  - Strategic Insight: Clear messaging and aggressive launch execution.
  - Outcome: Surpassed Pradaxa and became a global leader.
  - Key Lesson: Simplicity, when well-positioned, can be a powerful differentiator.

Case Studies

- Exubera (Pfizer) – Inhalable Insulin
  - Launch Year: 2006
  - Investment: $2.8 billion
  - Narrative: A novel idea—insulin without needles—but the device was bulky and poorly received.
  - Strategic Missteps: Weak market education, poor payer support, and negative public perception.
  - Outcome: Withdrawn from market after poor uptake.
  - Key Lesson: Innovation must be intuitive and well-communicated. Poor design and engagement can sink promising ideas

- Aduhelm (Biogen) – Alzheimer's Disease
  - Launch Year: 2021
  - Peak Sales: <$100 million (first year)
  - Narrative: First Alzheimer's disease-modifying therapy, launched amid controversy over efficacy and approval.
  - Strategic Missteps: Lack of stakeholder alignment, unclear data, high pricing, and payer resistance.
  - Outcome: Minimal uptake, price cuts, and reputational damage.
  - Key Lesson: Trust and transparency are critical. Without broad stakeholder confidence, even groundbreaking science can fail.

Conclusion

- Bringing new medicines to market is the ultimate cross-disciplinary challenge.
- It starts with visionary science and ends with human impact.
  Success lies in mastering the intersection—never losing sight of the science while executing flawlessly on strategy.
- The launch curve is steep, but with the right strategy, it can lead to a soaring trajectory.

- Start with Vision
  - Define who you are: innovator, generic player, or hybrid
  - Align product strategy with company identity and goals
- Integrate End-to-End
  - Connect R&D, clinical, regulatory, medical, and commercial early
  - Build products that are approvable *and* market-relevant.
- Active Learning & Adaptation
  - Treat launch as a "micro-battle"
  - Use fast feedback loops to adjust messaging, pricing, access
- Stakeholder-Centric Approach
  - Engage physicians, payers, and patients
  - Focus on education, support, and value demonstration
- Global & Local Balance
  - Craft a core global strategy
  - Empower regional teams to adapt tactics to local realities
- Realism & Resilience
  - Not every launch is a blockbuster
  - Learn from setbacks, adapt, and build long-term capabilities

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