LionBird

lionbird.com

SELLING TO PHARMA R&D

INSIDER CHEAT SHEET

LionBird

The pharmaceutical industry stands as a cornerstone within the healthcare ecosystem, boasting substantial revenues that surpassed $1.6 trillion in 2023, along with sizable budgets and escalating demand. At its nucleus lies the Research and Development (R&D) arm, tasked with pioneering new drugs and technologies. In 2022, the top 20 global pharmaceutical giants collectively allocated $139 billion to R&D efforts, yet faced a projected Return on Investment (ROI) of merely 1.2%, marking the lowest figure in thirteen years. Consequently, there's a pressing need to invest in tools and technologies capable of enhancing operational efficacy.

Annually, thousands of clinical trials unfold, spanning from initial phases to real-world evidence post-regulatory approval. Astonishingly, only around 8-9% of drugs embarking on this journey eventually reach the market. A pivotal area where pharmaceutical enterprises seek innovation lies in optimizing operational efficiency. In 2023, the FDA's Center for Drug Evaluation and Research (CDER) greenlit 55 new drugs. Notably, only 70% of trials progress from Phase 1, involving a limited cohort of healthy individuals, to Phase 2, where efficacy is gauged in patients with the target ailment. Roughly one-third of trials advance from Phase 2 to Phase 3, a phase akin to Phase 2 but with a substantially larger sample size. Approximately 25–30% of trials proceed from Phase 3 to Phase 4, where real-world evidence comes to light. This progression underscores the critical importance of real-world outcomes. Each clinical trial involves a multitude of stakeholders, from providers to Contract Research Organizations (CROs) responsible for trial infrastructure, necessitating adept navigation to secure successful pilots within the pharmaceutical sphere.

Traditionally, the pharmaceutical landscape has grappled with a shortage of internal talent to drive digital and data science initiatives. However, recent years have witnessed substantial internal investments in data science and engineering teams, perpetually exploring uncharted territories and thereby presenting opportunities for external vendors to contribute.

To help you better understand the development and sales process and its main requirements, we collaborated with a Biotech and Pharma R&D veteran to give you an insider's perspective on the needs and potential challenges when selling in this domain.

The paper is based on the conversation we had with Barbara Sosnowski.

Click on the preview to watch the full talk.

In this paper, you'll find questions to better understand the following:

Rise above the noise:

Evaluate how your solution will shine in the context of the Pharma R&D's relative priorities. Identify how it addresses specific pain points, optimizes their operations, or increases their likelihood to succeed in their core business.

Barriers to adoption:

Understand how your solution integrates into pharma's workflows and systems without interfering. Be prepared to navigate between multiple arenas including but not limited to clinical evidence, data collection and protection, safeguarding intellectual property, and defining pricing.

GTM strategy:

Gain insights into lead generation, different personas in the sales process, and contracting and pricing for the different product categories.

Footnote:
This Cheat Sheet isn't intended to serve as an exhaustive sales manual. Instead, it aims to offer a roadmap to assist you in navigating the various aspects of product development for Pharma R&D sales. Our goal is to help you comprehend the prerequisites you'll encounter upfront, such as privacy and intellectual property considerations, thereby enabling you to approach these lengthy processes with better preparation. Although contract specifics may vary among different types of companies, the question areas covered here are likely to be relevant to all companies developing solutions in this field.

Q1

How does your offering tie into pharma R&D departments' broader strategy and priorities?

1. Does your offering increase the number of drugs getting to market (both launched and in pipeline)?

2. Does your offering increase revenue from the approved drugs directly?

    2.1 What is the anticipated lifetime global revenue projected?

    2.2 Do you determine drug revenue via commercial assessment (i.e. performance of similar drugs in the market) or via economic studies?

3. Does your offering improve adherence and/or improve patient support strategy?

4. Does your offering enable segmentation?

    Did you identify subpopulations with unique characteristics, such as biomarkers and/or genetic markers who respond to the drug differently?

5. Does your offering generate an improvement in titration/dosing?

    In the case of diagnostic solutions, does it lead to high specificity/sensitivity (diagnostic) to support better outcomes in real world setting and in designing the trial (i.e. digital endpoints)?

6. Does your offering reduce operational costs?

    6.1 Are you influencing the process of trial recruitment and are you better able to match patients to the right drugs and/or sites? Do you reduce cycle time and/or improve throughput or production yield?

    6.2 Do you improve the utilization of resources, including staff, equipment, and facilities? (economy of scale)

    6.3 Do you improve energy consumption, raw material usage, and waste generation?

Q1

7. Does your offering reduce regulatory compliance, regulatory risk, and/or development risk?

   This impact can differ dramatically if you are developing a therapeutic solution and if you follow a known mechanism of action or a novel path.

   If you are developing a therapeutic solution, are you a first in class molecule or a best-in-class molecule?

Q2

Who is your champion – tactical & psychological barriers to the deal

1. Do you have sufficient financial stability to make it through a procurement and legal team vendor vetting process?

2. Are you presenting to the right person on the team (i.e. real-world evidence vs clinical vs scientific expert)?

3. Does the ideal starting point for conversation begin with senior innovation executives, managers of a business unit, or from an internal technical team?

4. What is the most effective means of reaching out to potential champions? Examples may include via scientific meetings, cold calls, networking, etc.

5. *In the case of AI driven diagnostic or analytic offerings:*

    5.1 What can your product do that dozens of AI researchers and software developers can't do internally?

    5.2 Are you saving the client significant computational costs?

    5.3 Are you expanding the patient population with your AI methodology?

    5.4 Will the internal data science team be a part of the decision making process?

    If you are developing a novel diagnostic or therapeutic approach:

    5.5 Are you competing with the current scientific approach in the company?

    5.6 Does it require training of internal R&D teams?

    5.7 Does your offering have a designated working environment for the internal R&D team?

    5.8 Who are your end users and how do they work with your buyers (if not the same stakeholder in the organization)?

Q3

What data do you need to start doing your AI magic? How will you obtain this data and protect it?

Data collection requirements:

1. How many data feeds and which data feeds does your product require?

2. What specific data fields are required for your product to function?

3. Is the data you ingest structured, unstructured, or both?

4. Is external enrichment required for analysis of customer-originated data (e.g., ontologies, standardized billing databases, clinical databases)?

5. Do the data feeds you own belong to the pharma, provider, vendor or both?

6. Is data exchange unidirectional or bidirectional? Between which systems? Is it read-only or does it require read-write capabilities?

7. How rapidly must data ingestion occur (e.g., real-time, minutes, hours, days, monthly)? How rapidly must your output be delivered to the user?

8. What types of ongoing support are necessary for new data feeds and modifications or changes to existing data feeds/schemas? Do you need to update the software? Monitor the model as new data flows in?

9. What other 3rd party systems do you need to integrate with / embed your service into for usability and to promote utilization? In what ways? (Ex Medidata or other CRO software, electronic health records, LIMS software)

Q3

Data protection requirements:

10. How far along are you in the ISO certification process?

    10.1 Several ISO standards are particularly relevant to the pharmaceutical industry. Will you require only ISO 9001, the standard for quality management systems or ISO 27001?

    10.2 Do you also need to obtain ISO 14001 for environmental management, or ISO 17025 for the competence of testing and calibration laboratories?

11. Are you SOC-2 compliant?

12. Are you GDPR certified?

13. Do you need to obtain data from the company or the CRO?

    13.1 How do you obtain this data?

    13.2 Do you need to standardize the data you receive or to provide tags or labels to it?

    13.3 Can you also work with unstandardized data?

    13.4 Does your product require uploading personal health information to the cloud? Is it kept in company servers at the clinical sites?

14. Have you identified all technology requirements up front and consolidated them into a simple summary page that can be shared early in the sales process?

15. Will company/partner employees be involved in the analysis of the product or technology? Will they need to update software versions over time as new clinical data enters or do they receive all the data upfront?

Some questions specifically for Diagnostic Platforms:

16. Is any special training or skill needed to perform the test? If so –

    16.1 What certification will technicians need to have?

    16.2 Does the test result need to be interpreted or analyzed by a medical professional (i.e. supervisor of the lab) or other trained person, or is this done via automation (e.g., AI/ML)?

    16.3 How long does the entire test process take? Is the result time-sensitive?

Q3

17. Will you own your own CLIA lab? If so –

    17.1 Will you do the set up and hiring of team?

    17.2 Will shipped samples require specific conditions?

18. Can samples or data be contaminated/ corrupted as a result of the collection process? Who supervises the scrubbing of the data?

    18.1 How will you measure cross lab reproducibility? Is there any special equipment that needs to be obtained to perform or analyze the test?

    18.2 For digital biomarkers - is the data being collected by medical grade vendors?

19. What is the output from the test process and how is this conveyed to the medical professional or patient?

Q4

What is the scientific validity of your offering?

1. What are the clinical applications of the test (if applicable)?
   E.g., diagnostic, prognostic, patient monitoring, treatment selection, and risk assessment

2. What evidence do you have on the efficacy of your solution? What is the scientific validity of the product? Has the Mechanism of Action been identified? Which of the below can you provide?

   — Surrogate for validated/medically accepted biomarker or test

   — Published studies

   — Unpublished studies

   — Validation of PPV/NPV (sensitivity/specificity) on different populations

4. How does the product compare to other existing solutions in the marketplace?

   Case 1: you run a diagnostic or therapeutic solution
   Have you tested your work in a head to head evaluation with the competition?

   Case 2: you offer a diagnostic
   Is there a commercially available diagnostic you compared your accuracy in relation to their specificity/sensivity?

   Case 3: you offer a therapeutic solution
   What is the safety data accumulated so far? Have you conducted toxicity studies? Have any side effects been identified?

Q5

Intellectual property – how do you protect your assets?

1. What is the core IP of the company?

    1.1 Will there be new IP generated during collaborations with Pharma R&D organizations?

    1.2 Will you be willing to give rights to this IP?

    1.3 What are the intellectual property (IP) protections in place? How does it differentiate from that of competitors? Are there any trademarks or proprietary technologies associated with your product?

    1.4 Who will own the insights and outcomes of the analyses of your offering?

2. FOR LATE STAGE COMPANIES – did you provide documentation from regulatory bodies? Do you have a complete hold letter?

    In the case of a therapeutic platform, did the FDA or EMA visit your manufacturing site in the case of a therapeutic platform?

3. Have you conducted freedom to operate assessments in all relevant geo locations?

4. How is your royalties schedule based on accumulated IP?

Q6

How do you price your offering?

1. Is the solution priced based on a SaaS user license, share of royalties, cost savings or based on shared revenues?

2. Is this engagement a one time or ongoing contract? Is this engagement for a specific project for this period in time and what are the upselling opportunities?

3. Is this solution sold by seat or by user or by site? What are the upselling opportunities?

4. In the case of identification of a new target or new IP related to the methodology, do you have ROFN (right of first negotiation) or ROFR (right of first refusal)?

5. How could the data and metadata you collect, to the extent you have rights to it, be used to generate additional value streams for third parties? Can it be relevant to an additional trial?

Questions specifically for Diagnostic Platforms:

6. Are there existing reimbursement codes which will cover this test?

7. Is there an increased effort led by competitors in this domain to gain reimbursement? For this modality?

8. Are there cost savings/avoidance which result from the test?

9. Does this test substitute for other tests/ processes which can be eliminated?

   Is there any comparable product on the market which might serve as a baseline for pricing?

10. Have there been economic studies based on real world data that serve as a baseline for building an economic impact model?

Q6

Questions specifically for Digital Endpoints:

Given the high cost of drug development, pharma companies have began utilizing novel digital endpoints that present a more precise and individualized measure to assess condition progression (better known as digital endpoints)

11. Will it substitute an approved FDA endpoint? How do you build a supporting database on the path for it to become a known endpoint?

12. If you have a solution that will substitute an FDA approved read out, how is it factored into the clinical trial as a regulatory finding?

13. When do you introduce your endpoint into a clinical setting in the process of the trial? Is it observational first? When do you engage regulatory bodies?

Appendix

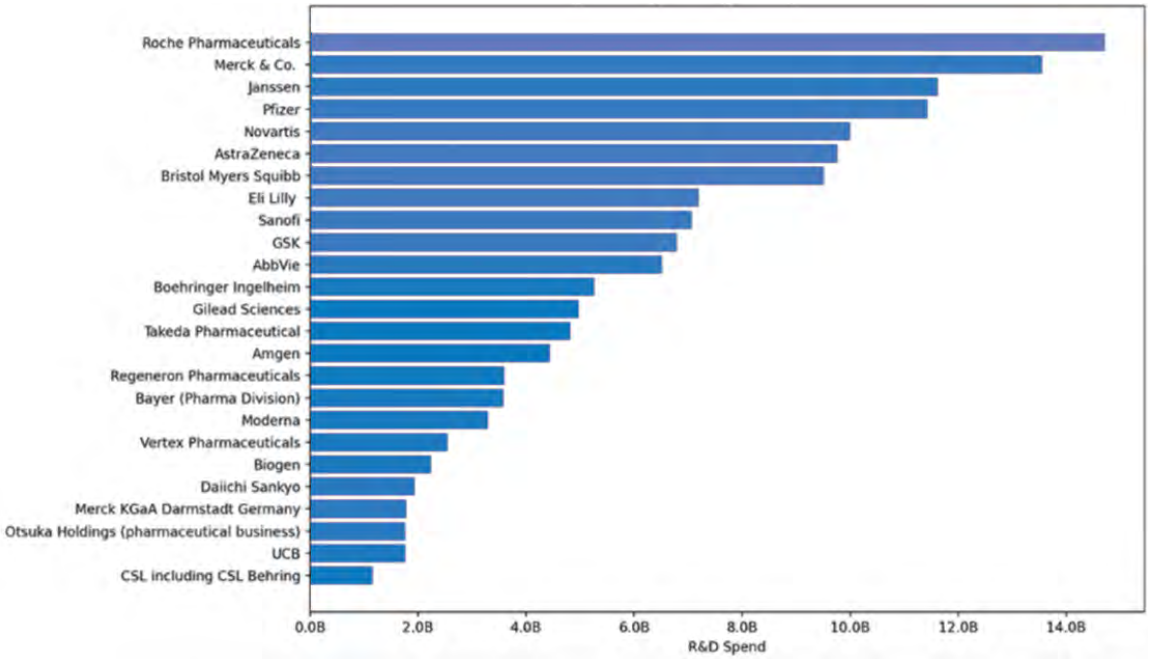
Top pharmas and how to identifty your targets

One of the things that are important to know is who you are looking to meet. Are you looking for professionals in clinical or medical affairs, business development, innovation, R&D, or scientists? They do not necessarily attend the same conferences apart from the large ones. However, if you are looking to attend conferences with the business development executives, the following conferences should be relevant.

When choosing who you want to meet at the conference, it's good to know the current financial state of your prospective clients. You can understand their current priorities and situation based on their publicly available financial reports from their websites as well as understand their drug development state based on active clinical trials they sponsor.

Link Top 50 pharmaceutical companies in terms of revenue for 2023

Link Top 25 pharmaceutical companies that spent most on R&D in 2022



Link Clinical Trial registry where you can segment existing and past clinical trials based on relevant criteria such as active, therapy modality, endpoints, trial sponsor, or inclusion or exclusion criteria.

Conferences

Link **JP Morgan Chase Healthcare Conference**
The biggest healthcare conference around. Where you'll be meeting (distracted) investors and all of the biotech and pharmaceutical industry with focus on innovations leads, venture arm and business development. Check out this post from our friends on how to prepare. Most importantly, it's invite only but don't sweat about the ticket. Most value add is meetings ouside and the evening receptions

Link **The Biotechnology Innovation Organization (BIO)**
The largest advocacy association in the world representing the biotechnology industry. Their conference takes place both in the EU and US.

Specific therapeutic area (TA) meetings

We wouldn't be talking about pharma without going to where your clients and prescribers are going (i.e the clinicians). Here is a small batch of sample conferences in specific therapeutic domains. Of course if you focus on a specific disease like IBD or Parkinson your offering must be present there as well whether in a booth, presenting a poster or giving a talk or simply networking with relevant clinicians, researchers, and pharma executives.

Oncology

ASCO American Society of Clinical Oncology

ESMO European Society for Medical Oncology Congress

AACR American Association for Cancer Research

Immunology

EULAR Annual European Congress of Rheumatology

ACR American Congress of Rheumatology

ACG American Congress of Rheumatology

CNS

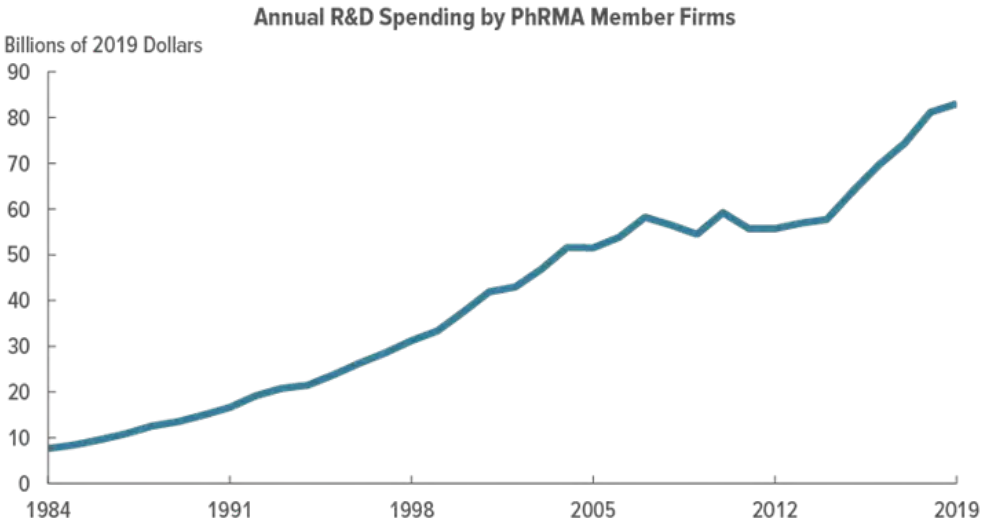
AAN American Academy of Neurology

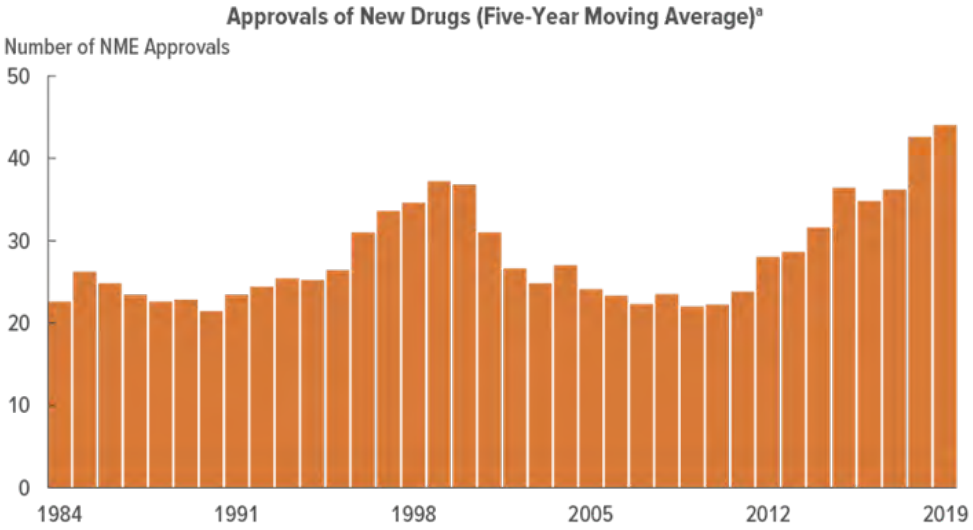
EAN European Academy of Neurology Congress

ANA American Neurological Association Annual Meeting

Publications

Link — Research and Development in the Pharmaceutical Industry summary from the congressional budget office. Great publication covering spending on R&D and the introduction of new drugs over the past few decades. The amount of money that drug companies devote to R&D is determined by the amount of revenue they expect to earn from a new drug, the expected cost of developing that drug, and policies that influence the supply of and demand for drugs among other factors.





Link — Here you can read a comprehensive report from industry leader IQVIA on growth opporurtinities in big pharma R&D by drug type, geographical region, and therapeutic area.

Link — Check out a PWC report on Next in pharma 2024: Reinventing for returns mapping key areas to innovate in data analytics and artificial intelligence, therapeutic areas that receive higher R&D spend, and M&A opportunities.

Recommended newsletters

Link **Endpoints News** – leading publication for biopharma with a great weekly newsletter covering recent trends and events in health, pharma, biotech, and drugs.

Link **Fierce Biotech** – Stay updated on all recent events happening in the medtech and biotech industries including recent investments and M&As and special reports for different client types. Don't miss a recent report on the 10 highest value R&D projects in biopharma here.

Link **Genome Web** – great resource for news and updates on genetics, genomics, and molecular diagnostics.

Authors

Barbara Sosnowski, PhD

Barbara is a former Vice President at Pfizer responsible for identifying innovative research opportunities spanning multiple therapeutic areas that are both strategically aligned as well as complimentary to scientific efforts within World-Wide Research and Development. She built and led a global team of 18 senior and executive scientists to identify First in Class or Only in class assets in innovative technology platforms. Barbara led multiple cross functional teams within Pfizer to conduct due diligence and present findings at both the WRD Leadership and Executive Leadership levels.

She is known for thinking creatively to solve challenges and for digging in-deep to get to the root of issues. She is a Pfizer Achievement Award recipient for recognition of visionary insights and innovation and held board member positions on Mass Bio, UCLA Technology Development Group, Molecular Stethoscopes and Ab Initio. Barbara currently sits as a board member for Kestrel Therapeutics.

Gal Noyman Veksler, PhD

Gal is a partner at LionBird and focuses on investments in pharma tech and precision medicine, women's health and behavioral health. Gal works closely with Nest Genomics, Mana Bio, Phase V, Maverick Medical and others.

Gal previously co-founded and led Neurolabs AI, a startup in opioid addiction, as well as served as the VP Business Development and Director of Healthcare of a global AI expert firm. Gal is a member of Kauffman Fellows (class 28) and holds a PhD in clinical and Neuro psychology specializing in chronic pain. She has co-authored ten peer reviewed publications in leading academic journals such as Vaccine and Psychiatry.

About Lionbird

LionBird is a venture capital firm investing in pre-scale digital health companies with operations in Tel Aviv and the U.S. Founded in 2012 by veteran entrepreneurs and Fortune 100 executives in the software and healthcare industries, LionBird provides pre-scale capital and assistance to mission-driven teams re-engineering the health status quo. Since its inception, the firm has invested in more than 35 founding teams and over $150 million in AUM.

To learn more about LionBird or to contact the team, visit www.lionbird.com.