New Product Planning Network

Stage Appropriate Insights Collections

February 28th 2024

Thunicia Moodley & Valay Desai

Steering Committee Members

New Product Planning
Network Group

Welcome to new Steering Committee Members

Thunicia Moodley

Aileen Salares

Catherine Symonds

NPP Network 2024 Schedule of Forums

Bi-monthly Event Extended to 90 Minutes

28 Feb-24

Stage Appropriate Insights Collections:

- Learn about market research fundamentals as well as KOL engagement
- Discuss the „right“ level of data/ insights for the right decisions

10 Apr-24

Strategy, Strategic Planning and Corporate Strategy 101:

- What is corporate strategy & how these roles differ
- How NPP impacts on corporate strategy

12 Jun-24

Early Stage Commercial Strategic Fundamentals:

- Join us to review that commercial fundamentals encompasse
- Discuss from case of scientific communication goals

4 Sep-24

HEOR & NPP for Global Access Planning

- How NPP & HEOR partner to build & execute global Access strategies
- Update to major US & EU policy and their impact on NPP responsibilities

9 Oct-24

Valuation Modeling, Sensitivity Analysis and Scenario Planning:

- how are these Leveraged in Decision-Making?
- Learn and discuss from case studies

4 Dec-24

Developing a Therapy in a Disease with no Treatment

- Through case examples, review what is unique and what is less unique about this treatment scenario

No calendar invitation yet? Let us know (anne.ollivier@sandoz.com)

New Product Planning Forum

Stage Appropriate Insights Collections – Feb 2024

Guest Panellists

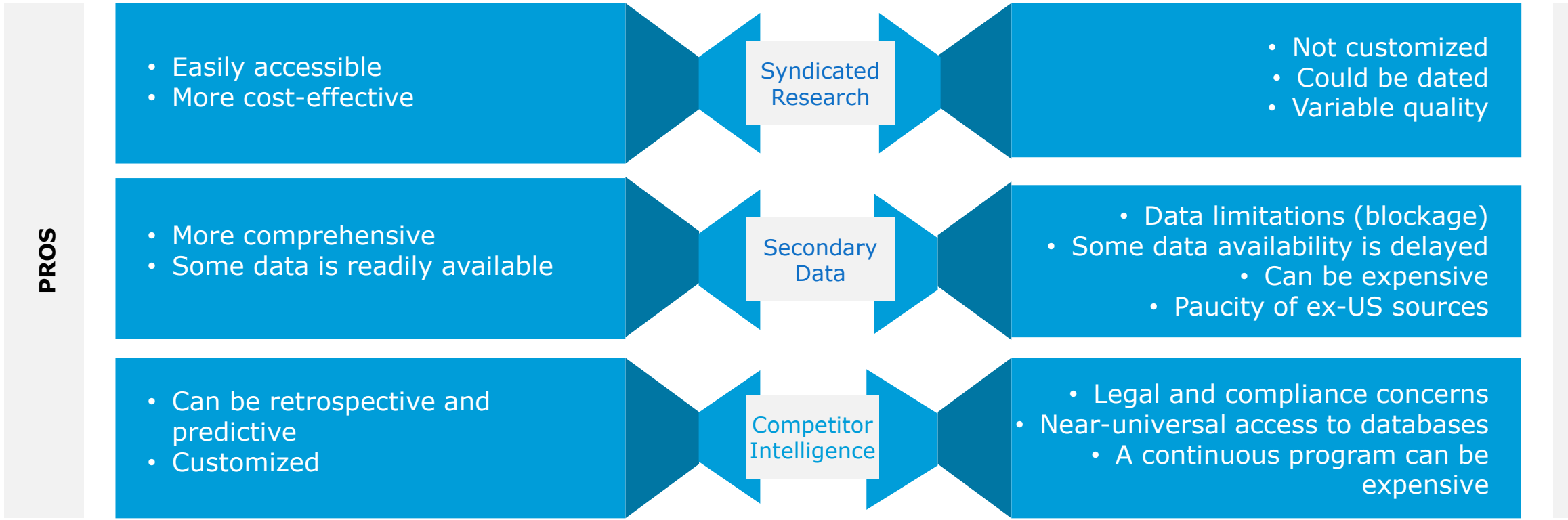
Ted Felix
Felix Insights Group
(FIG)

Patrick Park
Head of Insights & Analytics
(MR & NPP), Regeneron

Agenda

Topic	Presenter	Time
New Product Insights Activities	Valay	40 minutes
Q&A with Patrick, Ted & Audience	Moderated by Thunicia and Valay	25 minutes
Key Questions	Thunicia	10 minutes
Key Takeaways	Valay	5 minutes

Insights Collection (1)



Insights Collection (2)

Landscape Assessment & Unmet Need Analysis

Landscape & Unmet Needs

- What are the treatment landscape and treatment patterns in Disease A?
- What are the appropriate patient types and symptoms that are most relevant for treatment selection?
- What are unmet medical needs from KOL and non-KOL physicians' perspectives?

Product X Potential

- What is the potential for Product X in the treatment of Disease A? *Note that KOLs dislike doing market share allocation exercises*

Methodology

- KOLs, non-KOL physicians and other HCPs are typically interviewed. It is recommended to go broad in this phase of research. Include nurses, pathologists, office staff and other non-prescribers as appropriate

Patient Journey Research

Patient Journey & Treatment Decisions

- What defines the patient journey for Disease A sufferers?
- How does the patient journey differ based on patients' characteristics (e.g., age, disease severity, living setting)?
- What are the key drivers and barriers that influence treatment decisions and switches?
- What is the role of alternative treatment modalities?

Receptivity & Use of Product X

- What is the perceived value proposition of Product X according to each stakeholder (e.g., patients, physicians, other HCPs)?
- Which patient segments are likely to be most amenable to Product X?
- What are the key leverage points for Product X?

Methodology

- Research (IDIs, TDIs) is conducted with HCPs and patients. The sample is usually overweighted with HCPs. Qualitative patient journey research typically follows a stock-and-flow analysis (i.e., patient flow using claims data). Quantitative research with HCPs could be conducted as a follow-on to the qualitative research

Product Profile Testing

Product Attributes

- Valued product attributes and performance of each with current medications
- Future desired product attributes

Product X Profile Review

- Reactions to base case product profile, including likes & dislikes, efficacy, safety profile and estimated utilization
- Reactions to upside and downside cases

Methodology

- Qualitative research (IDIs, TDIs) is conducted with HCPs and occasionally patients. The sample is usually overweighted with HCPs. Patient profiles must be simplified such that patients who have a low health literacy (on average) understand them

HCP Emotional Insights

HCP Emotions

- Decipher Specialty N's mental and emotional schemata to explore and understand their motivators, barriers, psychogenic drives and unmet needs
- Understand the tensions and barriers in treating Disease A?

Opportunity for Product X

- Identify the level of satisfaction with current treatments of Disease A
- Identify opportunities and watch-outs for Product X at a brand level

Methodology

- Research (IDIs, TDIs) is conducted with HCPs. Use images (e.g., animals, vehicles) and descriptive characteristics that are attributed to them (e.g., turtle – slow-acting, German shepherd – loyal)

Patient & Caregiver Emotional Insights

Status Quo

- Understand how patients' emotions and hopes have evolved over the course of their Disease A journey
- Explore satisfaction with current and past treatment and uncover unmet needs in the category

Future Desired State

- Explore patients' hopes and expectations for future treatments for Disease A
- Uncover the opportunity for Product X by identifying the white space in the current and future market and ways to differentiate Product X from its competition

Methodology

- Research (IDIs, TDIs) can be conducted with patients and/or caregivers
- Online patient diaries can be deployed (to supplement IDIs and TDIs)
- Ethnographic research can be conducted (less common in Biopharma)

Payer Landscape Assessment

Current Management

- How do payers currently manage therapies used to treat Disease A currently?

Receptivity to Product X

- What will Product X's clinical and pricing comparators?
- What restrictions might be placed on Product X in the Disease A patient population?
- How will Product X be covered?
- What data needs to be collected for Product X on an ongoing basis to improve the product's coverage opportunity?

Methodology

- Research (TDIs) is conducted with payers: Medical and Pharmacy Directors at health insurers and PBMs. Other stakeholders as needed

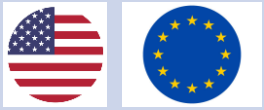
Other Market Research Studies Phase 2)

Study	Study Objectives	Regions (Common)	Regions (Less Common)	Type of Research
Dialogue Study	• Uncover unmet needs, examine conversational gaps and identify areas to improve communication			• Qualitative
Analogue Assessment Study	• Identify analogues and study their performance, including launch strategies + tactics			• Database mining & qualitative
Brand Story Research	• Evaluate potential pre-positioning platforms for Product X			• Qualitative
Influence Dynamics Research	• Understand stakeholder influence patterns associated with the treatment of Disease A			• Qualitative
Belief Mapping Research	• Map the ways HCP attitudes and beliefs impact management decisions for Disease A			• Qualitative

Other Market Research Studies (Post-Phase 2 and Pre-Phase 3)

Study	Study Objectives	Regions (Common)	Regions (Less Common)	Type of Research
Pricing Research	• Gauge revenue implications for Product X under a range of potential future scenarios and pricing options			• Qualitative and quantitative
Forecasting Research	• Assess Product X demand; simulate what-if scenarios given different clinical data and competitive scenarios			• Qualitative and quantitative
HCP Strategic Segmentation	• Uncover HCP segments and develop concrete strategies to meet their needs			• Qualitative and quantitative
Trade Name Research	• Conduct research with HCPs, patients, caregivers, pharmacists and other stakeholders on potential trade names			• Qualitative and quantitative
Colors & Logos Research	• Conduct research with HCPs, patients, caregivers, pharmacists and other stakeholders on logo designs and colors			• Qualitative and quantitative
Social Listening Program	• Collect social conversations and conduct analyses to develop customer insights along several variables			• Data scraping and analysis

Other Market Research Studies (Phase 3)

Study	Study Objectives	Regions (Common)	Regions (Less Common)	Type of Research
Decision Drivers Research	• Uncover behavioral trigger points and heuristics that drive diagnostic and prescribing activity			• Qualitative
Unbranded Message & Concept Testing	• Understand the optimal combination of unbranded scientific messages and concepts that persuade HCPs to seek alternative treatments for Disease A and which messages best link to creative concepts developed by agency			• Qualitative and quantitative
Patient Support Program Research	• Conduct research with registration study participants to uncover treatment experience and barriers to drug use			• Qualitative

Key Similarities and Differences

Primary Care Medicines (e.g., Type 2 Diabetes)	Specialty Care Medicines (e.g., Multiple Sclerosis)	Orphan Diseases (e.g., Sickle Cell Anemia)	Ultra-Rare Diseases (e.g., Danon Disease)	Oncology (e.g., Non-Small Cell Lung Cancer)
• Longer development times facilitates an unhurried approach • Differentiation vs. competitors is critical		• Less competitively intense • Shorter development times may require creativity • Market research for rare diseases can be more limiting (fewer potential respondents, compliance team-related limitations)		• Greater focus on patient segmentation in research (1L vs. 2L vs. 3L, biomarker-defined, etc.)
	• Earlier focus on research with payers and other stakeholders		• More focus on epidemiology validation	• Lesser focus on emotional insights work given oncology franchises
			• More focus on patient-finding activity	• Greater focus on patient selection and diagnosis (companion dx)

Key Decisions and Activities in NPP

Indication Strategy

- Disease Overview
- Define Unmet Need
- Define Initial Value Proposition
- Define Initial TPP*

Go / No Go to POC Trial

- Deep-Dive into Disease Overview
- Develop TPP Cases (Min, Target)
- Qualitative Market Research
- Market Sizing / Sales Forecast
- Early Economic Model
- Valuation Exercises / Business Cases

Go / No Go to Reg. Trial

- Refine Min. and Target TPPs
- Qualitative & Quantitative Market Research
- Market Sizing & Sales Forecast
- Pricing & Market Access
- Positioning
- Launch Planning
- Patient Advocacy

Preclinical to Phase 1 Programs

Key Decision: Defining Indication Strategy

Disease Landscape	TPP Development	Corporate Strategy	Value & Access	Indication / LCM Strategy	Market Sizing
• What is the current treatment practice & future competitive landscape for the disease? • What is the patient journey in the disease? • Who is involved in diagnosis and treatment?	• What are the patient segments / subtypes in the disease and associated unmet needs?	• How does this project fit with the corporate strategy? • How can the program help to shape future corporate strategy (e.g. build-up of know-how)? • Strategies related to therapeutic areas, diseases, and portfolio	• What is the value proposition in the disease (by country and public vs. private payers)? • What are the HCRU and treatment costs associated with the disease and patient segments? • What is the potential improvement over standard of care?	• What is the lead indication? • How should additional indications be prioritized?	• What is the right level of detail needed in a high-level estimate of the opportunity? • For start-up situations, this can inform valuation of the company

Reminder: Suggested tools and resources can be found in the Appendix (Link)

Phase 1 to Phase 2 POC Stage

Key Decision: Go / No Go to POC Trial

Disease Landscape	TPP Refinement	Corporate Strategy	Value & Access	Indication / LCM Strategy	Market Sizing
• What is the disease background? • What is the diagnosis & treatment approach? • What is the current & future pipeline? • What are the future trends that can impact the market?	• How should key attributes (safety, efficacy, etc.) be defined? • How should the Phase 2 be designed? • How can the Phase 2 demonstrate value?	• What are the corporate drivers for project advancement in PoC? • What role does this asset play in the portfolio? • What are the strategic options for this asset?	• What potential value propositions exist for payers? • Reimbursement landscape? • What evidence will payers expect? • What is the possible pricing corridor for the asset?	• What is the right initial Indication for this program? • How will this indication affect overall corporate strategy?	• What is the size of the current market? • What is the size of key patient segments? • What is the impact of future competition?

Reminder: Suggested tools and resources can be found in the Appendix (Link)

Phase 2 to Phase 3 Stage

Key Decision: Go / No Go to Registrational Studies

Disease Landscape	TPP Refinement	Corporate Strategy	Value & Access	LCM Strategy	Forecast Calibration
• Update competitor assessment • Refine assessment of patient journey • Understand drivers of new product adoption	• Revise TPP to Support a Competitive Program • Provide Key Commercial Input into Clinical Development Program	• Define the Commercialization Readiness Plan • Evaluate Resourcing Strategy to Support Launch • Build Critical External Relationships	• Refine Pricing Assumptions • Refine Understanding of Payer Landscape • Define HEOR Strategy	• Define and Prioritize LCM Options • Assess Impact of LCM Options on Price Potential	• Update Based on Landscape and TPP Scenarios • Update Based on Market Access Scenarios • Update Based on Targeted Regions

Reminder: Suggested tools and resources can be found in the Appendix (Link)

Key Takeaways

- New product insights are critical to New product planning
- There is no one-size-fits-all market research schedule. Focus on the business questions you need to answer to inform decision-making within the organization
- Market research, Analytics, Forecasting and Competitive Intelligence need to tell an integrated story
- Make sure to activate insights and have insights build off past work

Q & A Summary

1) What advice would you give an NPP professional that does not have a large budget to conduct primary market research or even purchase syndicated reports?

- Cost effective subscription options like First Word Biocentury can give you highlights of reports. You can get TA reports, e.g., oncology for five figures, which are cost-effective to start.
- Companies such as DRG & Clarivate have variable pricing models depending on the size of the company & revenue, offering initial lower costs to access.
- There are small vendors like M3, Sermo, or InCrowd that can do quantitative surveys at very reasonable costs - least expensive if you do the survey design yourself but they have reasonable prices relative to MR firms.
- With PMR, you have to think about the right size of sample, starting with small N No.'s for indicative data
- When organizing yourself, there are three cohorts: the things that we know, the things that we know we don't know, and the things that we didn't know that we didn't know. Think about what data will be confirmatory vs answering new questions. There's a wealth of information we can get through different resources, but confirming and gaining insight on attitudinally how experts and stakeholders feel about things is critical.

2) How can NPP professionals benefit from advisory boards that are primarily driven by Clinical or Medical professionals to meet their needs?

- Commercial should communicate the questions they need answered at the ad board to the primary participants. And they should list in as an observer.
- It is paramount that the internal clinicians separate their experiences from the current reality of the marketplace. The only hard and fast compliance rule regarding ad board participation is that salespeople cannot be involved. Outside of that, there should always be collaboration. We are gaining insights and advice to develop the most valuable and successful product that we can. Ultimately, it needs to succeed in the market to bring value to stakeholders (patients, providers, payers, investors, the company, etc.) *Everything that we do needs to have that lens.*
- It is critical that commercial fully participate in "clinical" ad boards. Commercial sets strategy and determines that value of different clinical paths and outcomes. Clinical decisions alter commercial potential and disconnection, and siloed activities wreak havoc on biopharma organizations. R&D and commercial need to partner throughout development to optimize the value of assets to stakeholders.

3) Do NPP professionals need to pay attention to payers? Can't they wait for an access person to join the company?

- In some companies the market research/insights professional will do the payer research and in other companies, there's an access strategy team that may do this research – the latter more likely in medium-large companies. Regardless of who does it, the payer perspective is key early on before you build the product profile and comparator arms for the pivotal trial. You need their input for PROs, endpoints, to ensure reimbursement/optimal price in different markets. If you can't bring on a full-time access strategy person early, maybe have a consultant that can give input early in the product development cycle.
- Also, you need to understand the marketplace at a high level even before this. Less granular research will suffice at this stage. Closer to launch, you will need a deeper dive with great granularity in launch market knowledge.

4) How much attention should NPP professionals pay to ex-US markets?

- There's a little bit of a pecking order where US is typically paramount, then the EU4, UK, and then Japan and China. If an opportunity is not viable for the US market, and unless there's regional incidence/ prevalence dynamics at play, the chances of it being viable globally are probably smaller. It's important to look at market sizing and growth potential by key market.
- Successfully engage counterparts in key markets early in the process; especially if it's going to be primary research, have them review materials and translations
- You pay attention to ex-US markets and bring the regions along but a lot of the research is done maybe at the regional level. E.g., you develop a global campaign and then the regional teams adapt for their purposes, BUT you do need input for the key/major markets when developing the campaign. With budgetary & timeline constraints we can't do research in every market in the world, but we can archetype, e.g., from a pricing and reimbursement perspective Spain and Italy are very similar. There are countries that are more driven by cost effectiveness like UK, Canada, and Australia.

5) Do the panelists or audience have any tips or strategies they've found particularly useful for insights in rare and ultra-rare diseases?

- HCPs, payers, patients, and caregivers are all our customers; collect all the different perspectives and think about the holistic view of the product or of the disease state.
- Working with patient advocacy groups (PAGs) in rare/ultra-rare areas can help with insight gathering.
- Work with collaborative partners such as Rare Patient Voice, who are tied into PAGs.
- Look for partners or consultants, vendors who specialize in rare diseases.

6) What has been the evolution of the NPP insights and analytics area since you have started doing this work?

- I've seen a lot of engagement and then I've seen sometimes a scaling back of engagement. In the past it was a very siloed approach, but now I think we are moving more into more harmonized, getting the new product team working with the clinical team as early as possible.
- What works well is working very closely with clinical and medical affairs and you're part of joint decision making bodies.
- To influence there's two key things. i) Providing the commercial perspective on key decisions by the highest decision-making body in your organization, e.g., what assets & trials to invest in, what indication to pursue, what countries to establish affiliates. ii) When you make those decisions, then where do you play, how do you win, i.e., defining the early commercial strategy.

- It's really evolved in terms of programs and investments. We've improved on making sure that from a MR and insights perspective, our outputs fit into the forecasting inputs and making sure that that's done in an effective way. Things are really changing and going to be changing even more with the advent of AI and chat GPT and things of that nature and our ability to come up the learning curve way faster than we ever did.

7) What advice would you give an NPP professional that does not have an insights, analytics, competitive intelligence or forecasting colleague to work with them?

- If we want insight & analytics to really get traction in NPP, and that might depend on the longevity of the function and the company, we should try to anticipate this discussion and portray the need. But doing that outside of budget cycle, making sure that we engage our stakeholders, that we can use the playbook to display what are going to be the needs for insight analytics and data along the journey, so that stakeholders and budget holders will get a greater appreciation. And we may need to message the need at different stages, but the better we're able to engage and get buy-in that we're going to need certain data, certain insight and budget along the way, the better we'll be equipped when we're facing the tough budget discussions.
- You don't necessarily need to hire a person and bring them on the payroll right away. You can have consultants to leverage on an as-needed basis. There are smaller independent consultants who are more cost effective than larger consultancies.
- Eventually you probably do want insights and analytics professionals who can do CI and forecasting, not to be absolved of the responsibility, but to have a thought partner. It’s very valuable to have that in the organization, but you’d have to have the portfolio that can support that level of effort.
- Getting to the insight and so getting a lot of information, a lot of market research is not the same as pulling out what's important strategically and bringing it to the program team. We have to do all these things, but we also have to know what the business question is, and how we’re going to use this. We must have someone thinking about product development to take what's meaningful from the research and translate it into strategy. NPP, compared with Marketing, has a little bit more bandwidth to get heavily into the research and really be sure that the right questions are being asked. It's certainly helpful to have a professional at the company who can help with the methodology and help take some of the weight off your shoulders because it is a lot of work. But if you don’t, try to look to vendors where there are senior people on the teams market research or consulting groups or that you can use as that thought partner.

8) What are some good secondary data sets for payer landscape assessment? What is usually the right time to conduct this assessment?

- In the US, MIT and FingerTip Formulary have formulary information. Trial Card has information on restrictions
- Eversana has Navlin, IQVIA has databases
- Ex-US pricing and reimbursement decisions, outcomes, global data by IHS
- Ex-US, HTA outcomes are publicly available in local languages
- Prism Access gives you detailed HTA information for 21 countries (including 10 European markets)
- Sermo has a strong payer panel to conduct primary MR

9) Could you clarify what business choices HCP emotional or attitude research influences early in the product life cycle where NPP plays, and then another question was the same regarding patient research?

- Physician research informs positioning. Emotional insights that lead up to positioning work may be further downstream, by the brand team. It’s premise, promise and proof - it's that unique place for your product in the mind of the customer's relative to the competition. We still need to understand the unmet needs and the drivers and the decision-making process because every decision we make is both cognitive and emotional. So that ultimately must start with NPP because you want to understand what problem, what solution is to be made with the new product and development and that it is truly addressing unmet medical need.
- Patients must be willing to accept the product, so we need this early research to understand how they feel and what they are looking for in a new treatment. The insights will also impact the direct patient website which will be developed later.

10) One thing that strikes me is someone working at a smaller company. We have two NPP folks, and our most advanced programs are in phase two. Some of these studies I see are done in the pre-launch phase, maybe two to three years from launch, which for me is further away from launch because we expect to have long phase three studies. So that timing of phase two versus phase three - could you speak to, rather than phase of development, how many years before launch would you typically do some of these studies?

- Forecasting research is fundamental for a phase three go-no go decision. You may end up never commercializing this drug because the board wants to sell the company. A market research-supported forecast has more credibility than one that lacks any MR.
- If you're a smaller company and several years away from launch, hold off on the trade name and colors and logos research, but keep in mind there's regulatory timelines. If they reject your trade name, the clock starts again. You don’t want to be in a position where you don’t have an approved trade name at FDA approval
- HCP strategic segmentation can be done in phase three
- You might not do the pricing research pre-phase three. For the go-no go decision you can rely on the payer landscape input to inform your pricing assumptions and do an analog assessment for the price point, and do the pricing research once you have phase three data.
- If the budget is limited there are things you can do that can get you closer to 90% of the way. There is an element of precision versus the 80/20 rule, so that you feel good about what you're doing without jeopardizing the quality of the work

Miscellaneous

- "Dampening", i.e., 35-50% discount of stated uptake to compensate for respondents’ overstatement, for forecasting inputs.