Aligning patient centred evidence generation across the drug development lifecycle

Naujoks C1, Olson M1, Doogan S2, Outeridge G2, Abrahamsen C2
1Novartis AG, Basel, Switzerland, 2Kinapse, New York, NY, USA

Introduction

• Insights are a synthesis of data and information, potentially from multiple sources, that contribute to an understanding of the true nature of a situation and support informed decisions and actions
• Patient insights are generated from patients (directly or indirectly) that provide deep understanding of patient perceptions, experiences and behaviors around their diseases and treatment

• They can help identify and explain why patients are doing what they are doing, and facilitate prediction of their unmet needs and behaviors
• Patient insights can provide answers to specific questions and / or test hypotheses, which can in turn translate into targeted drug solutions that better align with the voice of the patient
• They can help ensure that drug development programs are aligned with unmet needs and can help overcome access challenges pre and post-launch

Objectives

• To describe the types of patient insights that are most important to generate at different stages of the development timelines and the role they can play in achieving patient access

• To evaluate the different data sources and approaches that can be used to capture patient input and generate insights across the product lifecycle

Methods

• High level definitions into how patient insights can shape patient access across the lifecycle were developed
• The types of patient insights were mapped onto a framework modelled around the product lifecycle

Results

• The types of patient insights were observed to support access in a number of ways (see Figure 1) (illustrated with a number of case studies (data not shown))
• The types of patient insights that were most important to generate were found to vary across the product lifecycle (see Figures 2)
• During Early Development insights into the Disease Impact, Diagnosis Experience, Treatment Pathway and Treatment Unmet Needs are most relevant
• In the Pre-Launch period insights into Endpoint Selection, Indication Selection, Head-to-Heads Comparisons and Patient Subpopulations are most pertinent
• During Launch & Growth insights into Adherence, Long-term Outcomes and Follow-on Indications / Product Lifecycle Extension (PLE) are most relevant
• As an asset progresses through the lifecycle it is assumed patient insights will have been generated in the prior period – these insights need to be iterated to ensure they are kept up-to-date
• Traditional (e.g. Advisory Boards / Focus Groups, Claims / Pharmacy and Clinical Trials) and non-traditional (e.g. Social Networks, Tracker App and Wearable / Ingestible Devices) data sources and approaches for collecting patient insights varied greatly according to:  
  • Feasibility Assessment Variables (Noveltly, Sample Size, External Stakeholder Adoption, Cost, Time, Technical and Data Availability / Access Issues)
  • Strength of Evidence across Patient Data Variables (Patient Profile: Diagnosis, Comorbidities, Subpopulations; Disease: Clinical, Functional, Economic, Behavioral; Treatment: Adoption / Attrition / Switching, Outcomes, Adherence, Indications and Longitudinality) (see Figure 2)

Conclusions

• Non-traditional approaches, passive observation and / or retrospective analysis, demonstrated the ability to complement traditional approaches by providing additional granularity to the understanding of unmet needs
• Due to the more informal nature of non-traditional approaches, the ability to analyse data and generate robust insights was significantly more challenging. However, the overall timelines associated with generating patient insights from non-traditional approaches were found to be significantly shorter
• The case study analysis, showed the importance of non-traditional approaches in guiding traditional approaches through hypothesis generation

References


Conflict of Interest

• Naujoks C and Olson M are permanent employees of Novartis Pharma AG
• Doogan S, Outeridge G and Abrahamsen C are permanent employees of Kinapse Inc. and Ltd.

Funding

• The project was funded by Novartis Pharma AG, Basel, Switzerland