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Towards An AI-Enabled Social Media Listening Solution To Inform Early Patient-Focused Drug Development Strategies

Erica Spies
Director, Strategy Innovation & Capabilities
EMD Serono

Prathamesh Karmalkar
Lead Data Scientist – NLP, Text Analytics & AI
Merck Group

Presentation Overview

1) **Background**
   - ❑ **Patient Experience Data + Patient Focused Drug Development**
   - ❑ **Social Listening as a Method to Collect Patient Experience Data**
   - ❑ **Social Listening in Early Drug Development**
2) **Use Case: Social Listening in Early Development**
3) **Dashboard Demonstration**
4) **Next Steps**

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Patient Engagement (PE) & Patient Experience Data (PED) in Drug Development

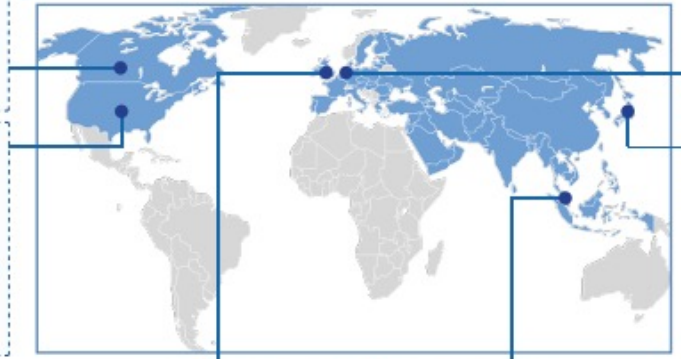
The development and use of patient experience data is one way to engage patients across drug development

Global alignment for consideration of PE & PED

"When people participate in the reviews, it adds to the **transparency, accountability, and credibility** of the recommendations made" - **CADTH** (2020)

"A **globally harmonized approach** to inclusion of the patient's perspective in a way that is methodologically sound and sustainable for both regulated industry and regulatory authorities" - **ICH** (2020)

"Revise PE methodology ... to reflect EMA's evolving approach to **patient data** and enhanced patient involvement." - **EMA** (2020)



"Advancing use of systematic approaches to collecting and utilizing robust and meaningful patient and caregiver input to **more consistently inform** regulatory decision-making" - **FDA** (2018)

"We want to see more **patient participation** in our drug review and pharmacovigilance activities" - **PDMA** (2020)

"When new applications for selected medicines are received, the applicant company will be asked for **evidence on the patient involvement activities** they undertook when developing their product." - **MHRA** (2021)

"Accelerating **systematic and meaningful** patient **involvement** in health systems is one of 6 strategic areas of focus in the Asia-Pacific" - **CoRE** (2014)

Source: Trends-in-the-Fast-Evolving-PE-PED-Landscape.pdf (patientfocusedmedicine.org)

Patient Experience Data for Patient Focused Drug Development (PFDD)

Opportunities for Social Listening Studies Across Clinical Development

Patient Experience Data Relevant to this Application (check all that apply)

1	☐	The patient experience data that were submitted as part of the application include:		Section of review where discussed, if applicable
2		☐	Clinical outcome assessment (COA) data, such as	
3			☐ Patient reported outcome (PRO)	
4			☐ Observer reported outcome (ObsRO)	
5			☐ Clinician reported outcome (ClinRO)	
6			☐ Performance outcome (PerfO)	
7		☐	Qualitative studies (e.g., individual patient/caregiver interviews, focus group interviews, expert interviews, Delphi Panel, etc.)	
8		☐	Patient-focused drug development or other stakeholder meeting summary reports	
9		☐	Observational survey studies designed to capture patient experience data	
10		☐	Natural history studies	
11		☐	Patient preference studies (e.g., submitted studies or scientific publications)	
12		☐	Other: (Please specify):	
13	☐	Patient experience data that were not submitted in the application, but were considered in this review:		
14		☐	Input informed from participation in meetings with patient stakeholders	
15		☐	Patient-focused drug development or other stakeholder meeting summary reports	
16		☐	Observational survey studies designed to capture patient experience data	
17		☐	Other: (Please specify):	
18	☐	Patient experience data was not submitted as part of this application.		

US FDA guidance on the 21st Century Cures Act of 2016 requires making public the use of PED in their decision making

[Assessment of the Use of Patient Experience Data in Regulatory Decision-Making Final Report (fda.gov)]

Patient-Focused Drug Development: Methods to Identify What Is Important to Patients

Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

February 2022
Procedural

VII. CONSIDERATIONS FOR USE OF SOCIAL MEDIA

Social media may be an approach to collect qualitative and/or quantitative data:

- Data can be collected qualitatively through passive observation of social media discussions or information; observations can occur retrospectively or prospectively.
- Data can be collected prospectively by administering a survey instrument in a social media setting. Best practices for designing and implementing studies using survey instruments and technology also are applicable to the use of social media to conduct a survey.

Consider the following when using social media data:

- Choose an appropriate research design.
  - Mixed methods sequential research designs can further strengthen the depth of knowledge gained from social media data.
- Carefully select the source(s) of the social media with the research question in mind, because findings across social platforms may be distinctly different (e.g., certain platforms may have strong advocacy/support community presence; others may predominantly capture industry/academic perspectives surrounding certain issues).
  - Different social media communities appeal to different segments of the population, and the degree of a community's user anonymity may affect what users are willing to discuss. Research using social media data should examine a variety of social media networks and communities to obtain data that can be most generalized to the population of interest to the extent possible (i.e., generalizability).[2] A discussion of the strengths and limitations of using social media data in qualitative, quantitative, and mixed methods research can be found in Guidance 1.
- Use appropriate methods to collect and analyze data.

[Final Guidance: Patient-Focused Drug Development: Methods to Identify What is Important to Patients (fda.gov)]

AI based Patient Focused Drug Development

What is PFDD?

As per FDA guidelines, Patient focused Drug Development is a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation.

The primary goal of patient-focused drug development is :

1. **Collecting robust and meaningful patient & caregiver inputs**
2. Facilitate patient enrollment
3. Minimizing the burden of patient participation in clinical trials
4. **Appropriate use of methods to capture information on patient preferences**
5. Potential acceptability of trade-offs between treatment benefit and risk outcomes
6. **Identifying the information that is most important to patients related to treatment benefits, risks, and burden**
7. Communicate the information to support their decision making

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Patient Focused Drug Development

Patients' increasing digital participation provides an opportunity to pursue patient centric research and drug development by understanding their needs

Fulfilling patients' needs to deliver a positive healthcare experience

Clinical needs

Diagnosis, treatment, disease management, delivery setting

Emotional needs

Managing anxiety and fear, caregiver expectations and involvement in decisions

Access needs

Access to hospitals, clinics, physicians, guidance on referrals, transportation

Information needs

Disease education, prognosis information, information on how to manage quality of life

Financial needs

Insurance coverage, prescription assistance, co-pay cards, etc.

Scientific education

Information on latest treatments, enrolling in clinical trials

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Patient Focused Drug Development

Use Cases of Social Listening in Drug Development (Koss et al., 2021)

1) **Identification and prioritization of unmet patient need to ensure that patient perspectives are represented early in the drug development process**
2) Characterization of the target-population to develop a target profile of a drug and to ensure that appropriate participants are recruited into a clinical trial
3) Repurposing of a drug; patients may report off-label use of medications on social media which could benefit drug repurposing
4) Recruitment of patients during clinical trials. Social media platforms can play an important role in reaching diverse patient populations
5) Detection of adverse events of drugs

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Patient Focused Drug Development

Social listening as a method to collect patient experience data

In the 2018 publication "Patient-focused drug development: Collecting comprehensive and representative input," and the Feb 2022 guidance document "Patient-Focused Drug Development: Methods to Identify What is Important to Patients," **FDA identifies two purposes for social listening** in early drug development:

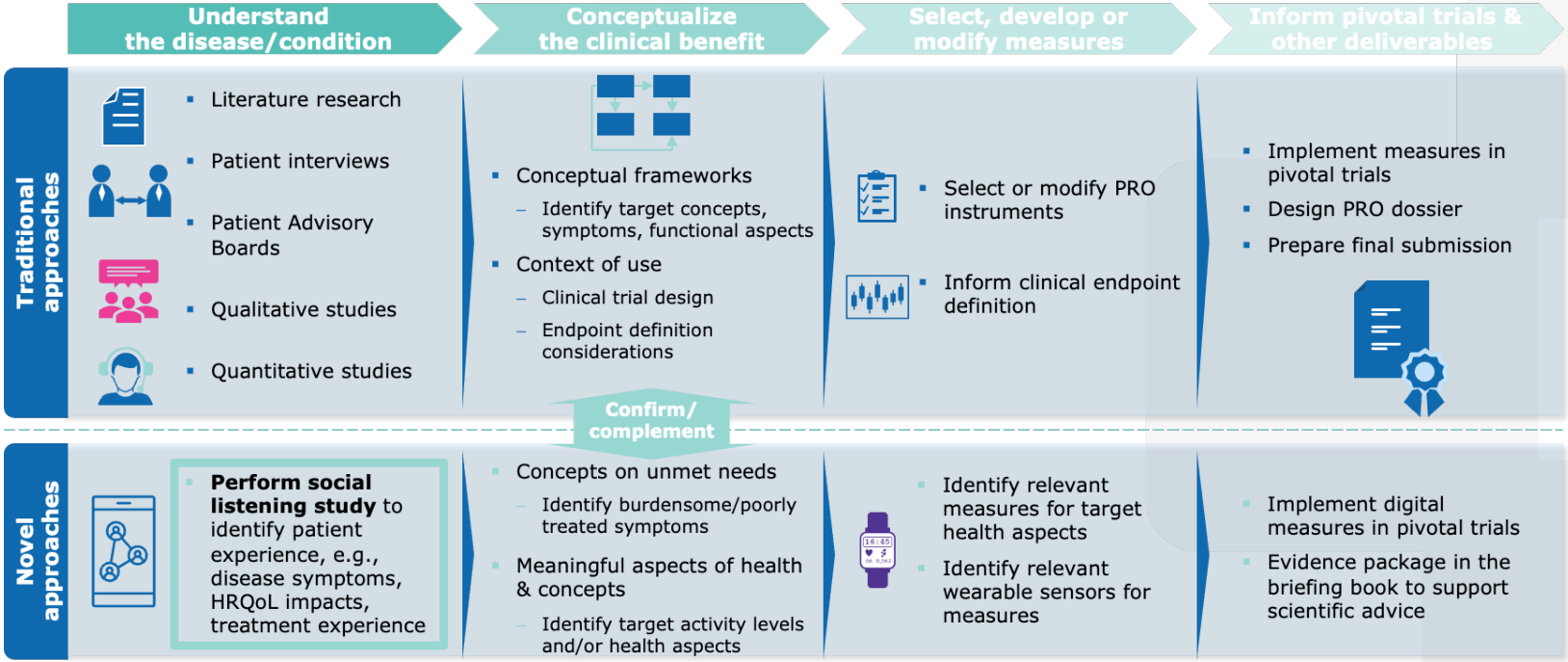
1) To understand the current landscape of a research problem
2) To supplement traditional research approaches (e.g., interviews and focus groups)

Indication	Company	Aim
COPD	Novartis	To assemble hypothetical treatment profiles to aid in PRO selection for clinical program
Dry eye disease	Novartis	To gain insights on disease burden, treatment patterns, and quality of life
Chronic kidney disease	AstraZeneca	To understand patient-reported experiences, symptoms, outcomes, and treatment management to inform design of observational cohort study
Inflammatory bowel disease	Takeda	To understand patients' assessments of risk and benefits associated with biologic therapies

Source: FDA (2018), own research (see references on page 18)

Patient Focused Drug Development

Social Listening is part of a broader evidence generation roadmap for patient focused drug development



Social Listening in Early Development

Research Questions of Interest

1. What is the overall level of health status/HRQoL of patients on standard of care as discussed by patients and caregivers in online platforms?
2. What is the level of satisfaction with the current treatment options?
3. **Given standard of care, what are patients' expectations relating to treatments? Which treatment attributes are most important to patients?**
    - What do treatments today not address from patients' perspective? What are gaps? Differentiate by treatment type by extent possible
    - To what extent can social listening describe patient experiences on different treatment regimens?
4. Which symptoms do patients experience most frequently?
5. **Which symptoms do patients find most burdensome?**
6. Which symptoms are still poorly managed by the existing treatment options, from the patient's perspective?
7. Which impacts do patients experience frequently? Which impacts do patients consider most burdensome

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*** Prioritized research questions are in bold**

Use Case Summary: Social Listening in Early Development

Overview of Challenge, Solution and Benefit of the Use Case

Challenge

- **Increasing digital participation** provides an opportunity to analyze patient experiences to **enhance research and drug development** by understanding the unmet needs of patients
- Leverage **social media-based patient experience** data for use in R&D through capturing and assessing patient **experiences and expectations**.

Solution

- **Systematic collection of social media** data for predefined search terms related to indications of interest
- An inhouse trained ML model for **categorizing posts into Patients, Caregivers & Not relevant** to identify patient focused data
- Additional in-house trained models **to extract treatments, psychosocial health, potential adverse events**, etc. to provide **additional insights from the data**

Benefit

- Analytical solution for end users for repetitive and near real time analysis of patient centric data
- Serve as a **foundational for the development PFDD** & Patient Centered Outcome strategies
- Ability to inform future R&D project teams **understanding of critical patient & caregiver experiences**

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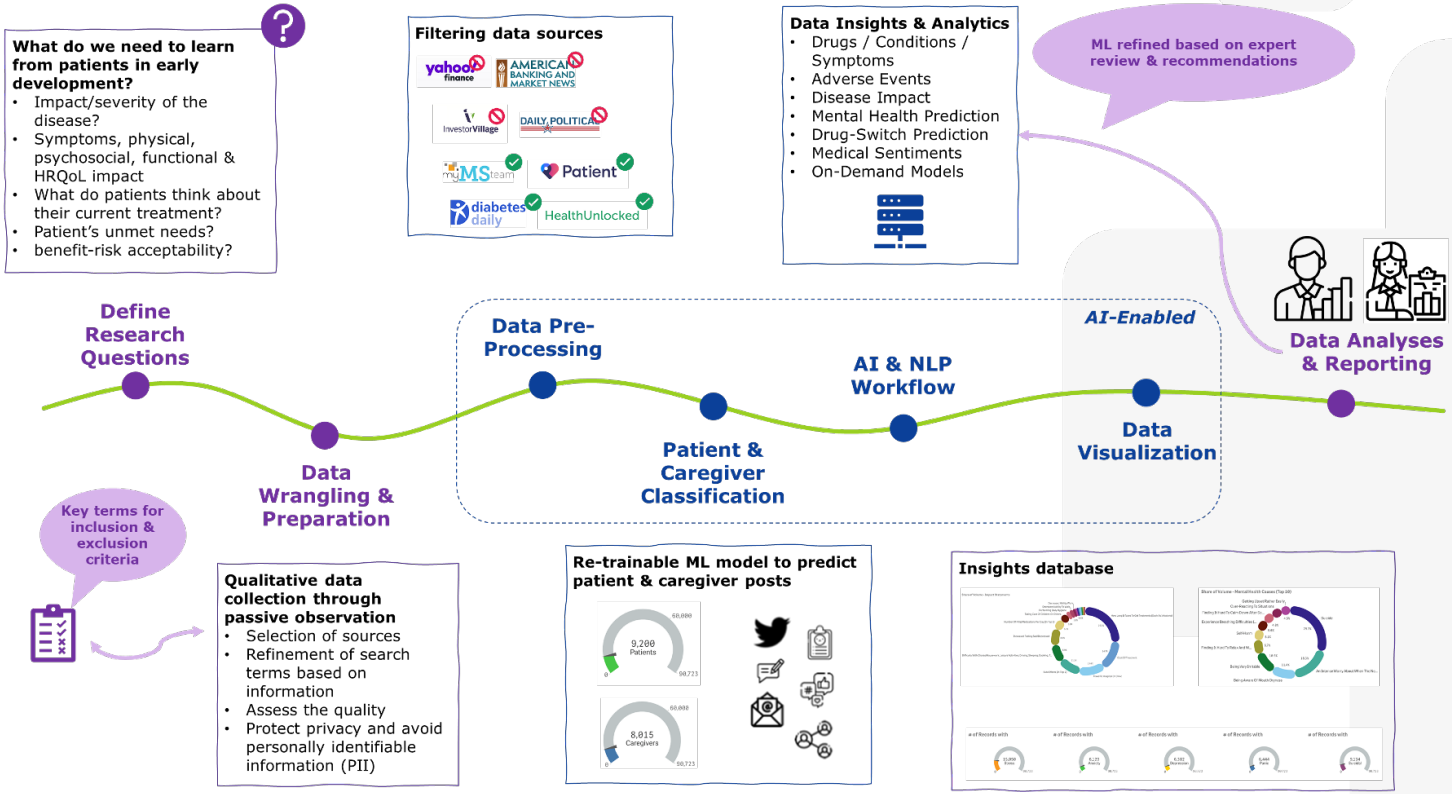
Social Listening in Early Development

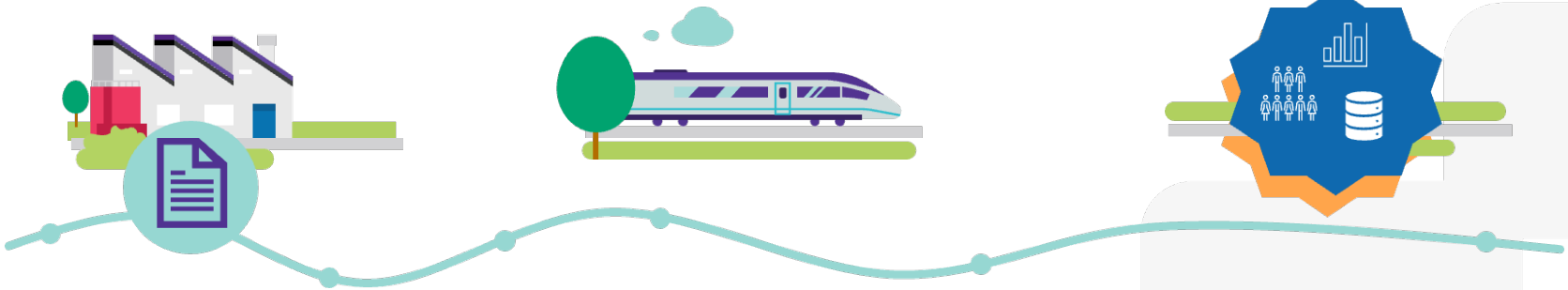
The HOW?



Dashboard Demo

We Are Just Getting Started.

Working Toward a Patient Experience Knowledge Hub



Finalize & Execute Report Template for Early Development Pilot

Finalize & Defend Social Listening Retrospective Study Protocol for internal governance approval

Communicate Pilot & Share Lessons Learned with GPTs

Technical and Conceptual Peer-Reviewed Publications

Extend into other indications & TAs

Inclusion of other data sources

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ISPOR Poster Link: Towards an Artificial Intelligence-Enabled Social Media Listening Solution to Inform Early Patient-Focused Drug Development Strategies | ISPOR Europe 2022, 6 - 9 November

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Presented by

John Snow LABS

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