

Patients and Patient Experience

- Explain the concepts of the patient, who is the patient, patient partners, caregivers, patient populations, and patient communities
- Discuss the concept of diversity and its impact on the patient experience
- Identify concepts of medical need and unmet medical needs for patients and patient communities
- Describe the concepts of natural history of disease and how natural history is captured and documented
- Discuss the meaning of disease burden in the context of patients', caregivers' and family members' lives
- Describe the patient experience in the health care ecosystem: diagnosis, access to care and treatment, disease management, outcomes, challenges, transitions of care, resources, and support
- Recognize the ever changing social, cultural, political, economic, and environmental impacts on the lives of patients, patient partners, caregivers, patient populations, patient communities, and perspectives relative to health care, treatment choices, and access
- Explain the concepts of patient groups, patient organizations, patient advocacy groups, including definitions/terms in use, historical evolution, roles, capabilities and functions in the healthcare ecosystem and patient experience

Foundational Concepts of Patient Engagement in the Medical Products Life Cycle (MPLC)

- Identify the types of common basic rights patients should have in their healthcare experience
- Discuss ethical, legal, and regulatory requirements when involving patients in research
- State the phases of the drug/medical product lifecycle (MPLC), including development, approval, and post-approval
- Describe the concepts, including the evolution, of meaningful engagement/involvement of the patient in the medical product lifecycle (MPLC)
- Explain the importance of meaningful engagement/involvement of the patient in the medical product lifecycle (MPLC), including potential benefits for patients, sponsors, and regulators
- Identify points throughout the medical product lifecycle (MPLC) where patient engagement is likely to have the most meaningful impact and ensure that patient needs are met
- Recognize the inputs/benefits that patients can contribute during appropriate times in the medical product lifecycle (MPLC)
- Outline the types of engagement/involvement that may be appropriate/effective at the likely points in the medical product lifecycle (MPLC)
- Explain the concept of representativeness and the importance of gathering input from broadly representative patient(s)
- Explain the science of patient input
- Summarize the current and evolving regulatory interest in and recommendations/guidelines for gathering and utilizing patient experience data in the medical product lifecycle (MPLC)
- Describe how to use the information gathered from representative patients to evaluate and validate other findings gathered from HCPs, surveys, and health economics and outcomes research (HEOR) data

Working with Patient Organizations

- Discuss the rationale for and value of partnering with patient organizations
- Identify existing open source resources that can be used to reduce uncertainty about terms of and conditions for partnering activities with patient organizations
- Discuss the importance of relationship building and maintenance, and engagement around mutually beneficial activities
- Evaluate organizational partners based on what stage the medical product lifecycle (MPLC) engagement is being sought, the lifecycle stage of the organization and the various functions of patient organizations play, as well as assessing their relevant competencies and skill in providing input at MPLC stage of interest
- List the basic elements of mutually agreed upon contracts/agreement

Patient Engagement Frameworks, Guidelines, Guidances, Standards, Good Practices

- Summarize the ethical, legal, and regulatory requirements and considerations for patient contact and engagement
- Recognize existing guidelines, regulations, codes, and other resources on appropriate conduct of patient engagement and interaction with patients, caregivers, and patient organizations
- Describe the legal and compliance concerns and sensitivities around patient engagement, patient member contact and communication, and interactions and collaborations with patient organizations
- Explain the patient's and caregiver's rights to fair compensation for time, effort, and knowledge sharing with a sponsor during the medical product lifecycle process
- Discuss the concept of patient/caregiver/patient group independence and prevention of conflict of interest situations

Organizational Readiness and Preparation

- Describe how an organization's mission, goals, objectives, policies, guidelines and processes within the R&D and commercial enterprises relate to patient engagement goals and approaches
- Describe approaches to determine attitudes about patient focus from leadership and key functional areas within the organization
- Identify methods used to assess the landscape of patient focus and patient involvement efforts within the organization
- Describe the knowledge, skills and resources that are typically needed to implement a quality patient engagement program
- Discuss approaches to influencing cultural change within the organization to encourage patient focused behaviors
- Describe the role of a centralized patient engagement function within an organization
- Discuss common organizational approaches to ensuring coverage of roles and responsibilities for patient engagement across multiple functions within the organization
- Outline how to establish appropriate goals and objectives for a comprehensive patient engagement program within an organization
- Review existing policies and identify key areas that require policies and guidelines to ensure a quality comprehensive patient engagement program
- Describe the impact of the collaborative process within the organization and with external stakeholders when developing a comprehensive patient engagement program
- Explain the program/project planning and development process
- Recognize informational and supportive resources for organizational capacity building, patient engagement program development, and patient engagement practices
- Discuss how to use sources of data to inform the inclusion of the patient perspective into key strategic initiatives

Patient Engagement Evaluation, Measurement, and Metrics

- State the importance of evaluation of patient-focused/patient engagement efforts
- Identify the key principles of evaluation
- Discuss the elements of patient-focused/patient engagement efforts that can be evaluated: Process, Quality, Outcomes, Return
- Describe the evaluation methods often used for each element of patient-focused/patient engagement efforts
- Discuss the process for developing patient engagement metrics, including setting objectives, defining expected outcomes, and identifying relevant measures
- Explain the methods used to develop data sources for patient engagement evaluation
- Express appropriate analysis and reporting of patient engagement evaluation data
- Describe effective dissemination and use of results of patient engagement evaluation both with internal teams and with external (patient, patient organization) participants