Patient Experience Dossiers: Strengthening Decision-Making with Patient-Centered Evidence

Patient Experience Dossiers are narrative reports in which patient organizations synthesize and contextualize disease-specific patient-centered evidence from multiple sources. They address the patient journey, disease burden, treatment experiences, patient-centered outcomes, and areas of unmet need – topics that regulators, payers, and other decision-makers have explicitly identified a stronger need for patient-centered evidence.

In this way, Patient Experience Dossiers are not only a resource for patient organizations, life science companies, and regulators, they are a strategic asset for manufacturers navigating an increasingly evidence-demanding payer landscape, where the patient voice is no longer supplementary but central to demonstrating product value.

PATIENT EXPERIENCE DOSSIERS CREATE VALUE BY:

Bringing the patient community's voice together: The dossier development process fosters collaboration among patient advocacy organizations, creating a common reference point and ensuring that a wide range of patient experiences and perspectives help shape the content.

Identifying evidence gaps: A structured, multi-stakeholder review of existing patient experience evidence against the dossier framework is a foundational component of the process. This review highlights where important patient-centered evidence is missing and guides strategies to strengthen the evidence base.

Providing a trusted and transparent evidence source: By consolidating lived experiences, preferences, and priorities into a structured and accessible format, the dossier serves as a credible reference for patients, advocates, researchers, policymakers, and manufacturers.

Strengthening access decision-making: Patient experience evidence is increasingly recognized as a key input into research, regulatory, and health technology assessments. The dossier equips patient organizations and other stakeholders with robust, evidence-based insights that can inform research agendas, regulatory evaluations, value assessments, clinical practice, and market access discussions.

For device and biopharmaceutical manufacturers, Patient Experience Dossiers provide a pre-competitive, patient-organization-led evidence foundation that can be strategically leveraged across the product lifecycle – from clinical development through market access and post-approval. Specifically, manufacturers can use dossiers to:

Inform clinical trial strategy and endpoint selection: Evidence gaps and patient priorities identified during the dossier development process can directly shape a manufacturer's clinical development decisions, from endpoint selection and patient-reported outcome instrument choice to trial eligibility criteria and comparator selection. Grounding these decisions in independent patient evidence strengthens the scientific rationale for study design and improves the relevance of trial outcomes to both regulators and payers evaluating the product's value.

Anticipate and respond to payer coverage criteria: Engaging in dossier development provides manufacturers with an early, independent read on which patient-centered dimensions are likely to arise in prior authorization, step therapy, and coverage policy discussions, enabling proactive evidence generation before those conversations occur.

Strengthen value assessment, health technology assessment, and formulary submissions: Patient Experience Dossiers can be cited in AMCP dossiers, ICER evidence submissions, and health technology assessment packages to substantiate patient-centered value claims with independent, credible evidence. Patient-reported outcomes and burden-of-disease data drawn from a dossier carry greater weight with public payers (e.g., CMS, NICE) and private payers alike when they originate from a patient organization.

Improving patient support programs. A Patient Experience Dossier's synthesis of lived experience, including treatment burden, adherence challenges, and gaps in disease education, gives manufacturers a clearer picture of where patients struggle beyond the clinical setting. This insight can be used to design or refine patient support programs, such as adherence tools, caregiver resources, or nurse navigator services, that address real-world needs and, in turn, strengthen the overall value proposition presented to payers.

Patient Experience Dossiers represent an important step toward a more patient-centered healthcare ecosystem, one in which patient perspectives are systematically captured, meaningfully integrated into evidence generation, and consistently considered in decisions that affect care, treatment access, and health outcomes.

For device and biopharmaceutical manufacturers, Patient Experience Dossiers provide a pre-competitive, patient-organization-led evidence foundation that can be strategically leveraged across the product lifecycle – from clinical development through market access and post-approval. Specifically, manufacturers can use dossiers to:

Patient Experience Dossiers represent an important step toward a more patient-centered healthcare ecosystem, one in which patient perspectives are systematically captured, meaningfully integrated into evidence generation, and consistently considered in decisions that affect care, treatment access, and health outcomes.

RESERVOIR HEALTH

apx applied patient experience™

CONTACTS
Allison DeBattista | adebattista@reservoirhealth.com
Gretta Stone | gstone@reservoirhealth.com