

Tools to Support Sponsor-Patient Engagement: Fair-Market-Value (FMV) Calculator and Engagement Templates

OVERVIEW

The NHC wants to ensure that all stakeholders confidently enter into ongoing, compliant, and sustainable engagement efforts that effectively drive health care innovation based on patient and caregiver insights, which must be collected in a trusted and high-quality manner. This project aims to support sustainable agreements between stakeholders and the patient and caregiver community as part of medical product development by:



1. Developing, for U.S. use initially (adding other countries in the future), a fair-market value (FMV) calculator for compensation of patients and patient groups involved in “patient engagement activities” taking place between patient organizations and/or unaffiliated patients and private companies. The final product will be a calculator that companies can use and further customize for their own needs. Also, building blocks, such as engagement activities and principles, will be included.
2. Adapting, for use in the U.S., the Conflict-of-Interest Principles and Privacy Principles (with examples) developed by the E.U. Patient Focused Medicines Development (PFMD) initiative to create standardization across all activities.
3. Adapting, for use in the U.S., the contract templates developed by PFMD to simplify and standardize the process for patient and patient groups.

PROCESS

Stakeholder Engagement: The key stakeholders for the project will include patient advocacy organizations, medical product companies (pharmaceutical, biopharmaceutical, diagnostic, and device), trade associations, government agencies, research organizations, and other relevant parties as identified over the course of the project. Stakeholder input will be sought throughout, including through in-person meetings, virtual collaboration, and targeted interviews and focus groups.

Steering Committee: The program will be guided by a multi-stakeholder Steering Committee that includes sponsors, patients, and content experts.

Environmental Scan: We will conduct research and stakeholder outreach to understand, analyze, and document all relevant stakeholder interests in tools for sustainable patient engagement agreements, as well as relevant compliance and regulatory considerations that will shape the design and development of the tools.

Gap Analysis: We will also conduct a gap analysis to identify additional complementary or adjacent tools that do not yet exist that could aid the development of sustainable patient engagement agreements. This will serve as an independent resource and guide for potential next steps to further enhance patient engagement.

The NHC will utilize outputs from this program to inform its public policy and advocacy work. This project is expected to be completed by early fall 2019. For more information, contact Silke Schoch at sschoch@nhcouncil.org.