

Track 12 | Value and Access



The healthcare landscape is evolving into one assessed on value, and there is a need to understand the impact of this movement on all stakeholders: providers, payers, biopharma, and patients. Value and access to medicines are complex issues that require analysis from health economic and philosophical perspectives. The Value and Access track will bring together global regulators, industry leaders, academics, patients, and payers who will facilitate discussions and address questions such as:

- What information and evidence are being used to define value?
- What are the ethical considerations when determining access to medical products?
- Do strategies that increase diversity and inclusion in clinical trial research improve access to medicines? Who is making or influencing access decisions?
- How can real-world data be leveraged to drive access to medicines?
- What are the regulatory and legal considerations

DIA recommends this track and associated sessions to payers, bioethicists, health economics outcomes researchers, health economists, statisticians, data modelers, clinical researchers, post-marketing professionals, and regulatory affairs professionals.

Included Topic Areas

Comparative effectiveness research, diversity, equity, and inclusion, ethical considerations in clinical research, health technology assessment, real-world outcomes, value-based healthcare; drug pricing, reimbursement and access, commercialization, product lifecycle considerations. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

- 1. Paying for What Works: Value-Based Contracting (VBC) Between Payers, Manufacturers, and Providers—Where Do We Go from Here?**
 - a. VBCs (Value Based Contracting) and subscription models within state
 - b. Paying for outcomes within Medicare and Medicaid
 - c. How VBCs have panned out for pharma and commercial plans"
- 2. Planning Studies to Meet Both Regulator and Payer Needs**
 - a. Choosing endpoints that matter for coverage decisions and ensuring access
 - b. Balancing the needs of clinical trial participants versus commercial outcomes
 - c. Payer/regulator engagement within studies
 - d. FDA and Centers for Medicare and Medicaid Services (CMS): Parallel Review
- 3. Pricing and Access Determinations: When and How to Engage Stakeholders (patients, payers, HCPs, etc.) During Drug Development Process and During Formulary Decisions?**
 - a. Potential options to engage and solicit input during drug development
 - b. Engaging stakeholders during development of pricing
 - c. Engaging stakeholders during development to ensure equitable access to products
 - d. How patient groups, community leaders, academia, investors, and industry are adjusting to challenging market conditions to continue to drive therapeutic innovation
 - e. What are the factors that most influence patient access (i.e., regulatory bodies – FDA, NCCN, cost/payers alone, physician preference, clinical evidence, etc.)
- 4. Impact of Value Frameworks and Evidence-Based Pricing (with ICER, NICE)**
 - a. Potential impact on overall pricing decisions
 - b. Promising strategies and considerations"
- 5. Supporting Access to Treatments in Developing Countries**
 - a. Policy updates on drug pricing: regulations and legislation
 - b. Strategies to enhance clinical research in developing countries
 - c. Key and structural barriers to address with healthcare disparities
 - d. Promising pricing and access strategies (e.g., COVID-19, gene therapy, rare diseases)
- 6. Using Real-World Evidence for Real-World Payment**
 - a. How can real-world data drive reimbursement and/or increase market access?
 - b. What real-world data demonstrates "value" to both the patient and sponsor?
 - c. Who "owns" data when the patient changes plans, stops treatment, or is "cured"?
 - d. Strategies for data sharing, database linking (e.g., EMR-claims), and maximizing EMR data
 - e. Strategies for the ethical collection, curation, and analysis of data