Can you provide an overview of what the AMCP eDossier platform is?
The AMCP eDossier System at Formulary- Decisions.com is a centralized web-based payer ecosystem provided by Dymaxium in partnership with AMCP. It is a one-stop shop for resources and tools to support formulary decisions. It connects current and future health care decision makers (HCDMs), including payers, with evidence from leading scientific sources and pharma companies (ie, pharmaceutical, biotech, and medical device manufacturers), insights from health technology assessment and other authoritative reviews, and tools to support evidence-based product evaluations and decision-making processes.

What led to the need to develop this platform for health care decision makers?
Historically, there was a need for payers and other decision makers to better utilize dossier information from pharma companies, as well as a need for single source, centralized dossier access. In 2011, Dymaxium and a steering committee of leading health care decision makers (HCDMs), including payers, with evidence from leading scientific sources and pharma companies (ie, pharmaceutical, biotech, and medical device manufacturers), insights from health technology assessment and other authoritative reviews, and tools to support evidence-based product evaluations and decision-making processes.

Can you explain the methodology behind the platform (how does it work, what kind of information sources are used)?
Health care and formulary decision makers (ie, payers and other health care decision makers) select the product they want to review and evaluate. The System then aggregates all the evidence, insights, and tools on one product page. The evidence is generated from using the platform’s proprietary meta-search engine to dynamically provide the latest evidence links from 25+ public sources (PubMed, FDA, JMCP, etc.), and proprietary partner resources (The Medical Letter, Pharmacist Letter, DRG Fingertip Formulary, Advera Health, etc.). The System also provides insights on evaluations and reviews from third party sources (NICE, CADTH, ICER, etc.).

In addition, the System provides users with a centralized eRequest tool that enables them to make FDA-compliant unsolicited requests to more than 300 pharma companies for more than 2000 products. Pharma companies can use a pharma version of the system to respond to the requests with their information (AMCP dossier, economic models, etc.) and/or use interactive eDossier tools integrated with P&T monograph, slide deck, and comparison tools.

The FDA recently released guidance for sharing health care economic information (HCEI) between payers and pharma companies. Was this guidance in line with AMCP and the mission of the eDossier platform?
Yes, this guidance is in line with AMCP and the mission of the eDossier System. AMCP has taken a leadership position to improve the sharing of HCEI between payers and pharma companies, providing input and recommendations to FDA, coordinating FDAMA 114 partnership forums with all stakeholders, and with its AMCP Dossier Format v4.0 updates.

The mission of the AMCP eDossier System is to support the evidence and information needs of payers, including the exchange of HCEI between payers and pharma. Currently the System uses the AMCP dossier format, which contains an economic section with HCEI analyses (budget impact, cost-effectiveness). The system also currently allows pharma companies to upload supporting clinical and economic files (including HCEI spreadsheet models).

How has the platform been received by payers? What is the feedback like?
The AMCP eDossier System has been very well received by health care decision makers. The System has grown steadily in both its user base and utilization since the launch, and currently has more than 1600 payers and other HCDM users. Since the expansion of the System in 2014, the number of users has doubled over previous years. In 2016, usage activity on the system experienced
a 26% increase in number of hits, compared with 2015, and a 138% increase in number of unsolicited requests, vs 2015. Recent feedback from users (n=66) includes the following:

- 80% stated that the System is easy to use;
- 44.7% said the System saved them 1 to 2 hours in product evaluation, while 27.7% said the System saved them 2 to 5 hours;
- 64% said it is easy to specify what is needed from manufacturers; and
- 46.8% were satisfied and 38.3% very satisfied with manufacturer dossier.

As we continue to improve and evolve the platform, we have engaged with users in 2016 for feedback on what else the System could do to better support them (n=113):

- 75.9% want more eDossiers on the system
- 51.9% want preapproval information
- 46.3% want more pre-populated P&T Prep templates

At the recent AMCP Nexus conference, we introduced new features to directly address this feedback, including more eDossier options for manufacturers, preapproval support for pipeline information and pipeline dossiers based on AMCP Format v4.0, P&T Planner tool to help users plan 18 to 36 months preapproval, and pre-populated P&T Prep sheets for the most requested pipeline products.

**How well is platform functioning to connect payers with the information they need for preapprovals?**

The System has evolved to better connect payers with their preapproval information needs. The System now automatically adds pipeline updates from the FDA and corresponding product pages. The System also provides proprietary P&T Prep Sheets for select pipeline products as a starting point for payers’ review in preparation for formulary decisions. The P&T Prep Sheet content development is created by a team of P&T analysts and reviewed and by a managed care pharmacist prior to posting. The content includes a product review, clinical trials publicly available to date, and economic considerations.

From a pharma company perspective, the platform has been enhanced to support AMCP Format 4.0’s guidance on preapproval information. This means that pharma companies can either provide select preapproval information and/or pipeline dossiers. The capabilities of the system are ready for any manufacturer to provide full support at the preapproval level. However, this is in accordance with the companies’ current regulatory processes, and any information provided still requires an unsolicited request from the HCDM user.

In relation to the usage of the System, we have user feedback that directly relates to the exchange of information between payers and manufacturers, particularly in the preapproval stage. In a survey conducted in November 2016, of the 172 respondents, payers, and other health care decision makers involved with the formulary decision making process:

- 92% said that the unsolicited request process within the System met or exceeded their need to support the information exchange between manufacturers and decision makers pre-approval (n=106).
- 97% responded positively to the ease of use of the eRequest Tool within the System to request preapproval information from manufacturers (n=109).
- 86% said that the System currently provides sufficient tools and information for pre-approval (n=107).

**Who can access the eDossier? Do health care decision makers have to pay to use it?**

The use of the AMCP eDossier System is free to registered HCDMs and is based on the following qualifications:

- HCDMs who are actively involved in making formulary and/or benefit design decisions can register to access the general System; and
- Access to each specific eDossier must be initiated by an unsolicited request from a HCDM to the manufacturer using the eRequest tool or in accordance with the HCDM’s instructions provided through the P&T Planner; and
- Manufacturers decide if a HCDM is allowed to access specific product eDossier on the System.

The AMCP eDossier System is password protected and is not accessible to the general public. The users are registered HCDMs whom, once qualified, can specifically access this System.

**Are there any other aspects of the AMCP eDossier that you’d like to highlight?**

The AMCP eDossier System is a unique, one of a kind System specifically designed for the payer community. It provides a secure experience in which payers and other decision makers can interact within the System; and the System supports and observes the FDA’s unsolicited request requirement for dossiers, as well as ensures the integrity of the information exchange for the manufacturers. It closes the loop on the process by providing a feedback mechanism for manufacturers so they can continue advance and support quality information to meaningfully support the formulary decision process.

The platform continues to evolve to meet the broader needs of our payer users, and our pharma customers. For payer users, we continue to add more content and tools to support their workflow needs and help them work more effectively and collaboratively. For pharma customers, we continue to broaden the evidence and information exchange capabilities, and provide them with unique ways to engage and gain insights from the payer community.