A Descriptive Analysis of Healthcare Decision Maker Engagement Patterns in Pre-Approval Information Exchange

Minha Choi, PharmD[1]; Annie Chang, PharmD[1]; Claire Gorey, MA[1]; Breanna Penzner, PharmD, MS[1]; Jackie Gladman[1]; Amy Duhig, PhD[1]

[1]Xcenda, LLC, Palm Harbor, FL, USA

BACKGROUND

- Pre-approval information exchange (PIE) is the communication of unbiased, factual, accurate, and non-misleading information between drug and device manufacturers and healthcare decision makers (HCDMs) (payors, formulary committees, and similar entities) prior to Food and Drug Administration (FDA) approval.[1]
  - The type of information shared can include items such as factual presentations of clinical trial data, product pricing information, and product-related programs and services.
  - PIE provides an opportunity for drug and device manufacturers to engage proactively with HCDMs about unapproved products or unapproved uses of approved products and helps HCDMs budget for future coverage and/or reimbursement decisions.
- FormularyDecisions (FD) is an online platform that facilitates the exchange of clinical and economic information between drug/device manufacturers and HCDMs throughout a product's life cycle.
  - FD provides HCDMs a centralized resource for product evaluation and enables drug manufacturers to understand HCDM perceptions of their products via HCDM feedback and HCDM activity metrics.
- Over the past 2 years, manufacturers have received more guidance on appropriate exchange of pre-approval information, which has facilitated bidirectional communication.
  - In June 2018, the FDA released a final guidance (Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions) on how drug and device manufacturers may communicate information with HCDMs, including the dissemination of pre-approval information.[1]
  - In January 2020, the Academy of Managed Care Pharmacy (AMCP) released Version 4.1 of the AMCP Format for Formulary Submissions, which included guidance on unapproved use dossiers that manufacturers may use for conveying evidence on unapproved medicines and indications submitted for FDA approval.[2]
- Despite availability of pre-approval content on the FD platform and recent release of the FDA and AMCP guidances, no previous research has investigated the timing and patterns of HCDM engagement with pre-approval information on the FD platform. An exploration into the timing and patterns of HCDM engagement in PIE is warranted.

OBJECTIVE

- To retrospectively evaluate registered HCDMs' patterns of engagement on the FD platform related to pre-approval products

METHODS

- New molecular entities (NMEs), biologics, biosimilars, and supplemental indications approved in 4 key therapeutic areas: hematology, oncology, central nervous system (CNS), and immunology during 2018 and 2019 (with HCDM activity captured 24 months before approval of the given drug) were included.
- Four metrics on the FD platform were evaluated to identify patterns in HCDM engagement 24 months prior to and after product approval: 1) Product Page hits, 2) HCDM Watch List additions (adds), 3) Dossier Requests, and 4) Prep Kit hits (**Table 1**).

Table 1. Definitions of Features and HCDM Activity Metrics on the FD Platform

Key Trend	Definition
Product Page	▪ Product-specific home page on the FD platform
Product Page Hits	▪ HCDM clicks on the Product Page
Watch List	▪ List of products that an HCDM may choose to follow on the FD platform ▪ HCDMs receive an email or are alerted within the platform when information becomes available for products on their Watch List
Watch List Adds	▪ Product followed on the FD platform by HCDMs
Dossier Requests	▪ HCDM-driven requests for an eDossier*
Prep Kit	▪ Research analyst-prepared information kit containing publicly available evidence for specific pre-approval products ▪ The Prep Kit is designed to help HCDMs in the drug review process
Prep Kit Hits	▪ HCDM clicks on the product's Prep Kit

*The eDossier is digitized on the FD platform.
Key: FD – FormularyDecisions; HCDM – healthcare decision maker.

METHODS (cont.)

- Four outcomes were evaluated in the analysis:
  - Time to initial HCDM engagement was measured using the mean time (months) to first Product Page hit, Watch List add, Dossier Request, and Prep Kit hit within a 24-month period before the product's FDA-approval date.
  - Trends in HCDM engagement over time were measured using the mean number of Product Page hits, Watch List adds, Dossier Requests, and Prep Kit hits during 4-month intervals within a 24-month period prior to the product FDA-approval date.
  - Time to HCDM uptake of pre-approval information was measured using the mean time (months) to first Prep Kit hit during a 24-month period after the Prep Kit upload date.
  - Effect of pre-approval information upload on HCDM activity was measured by comparing mean Product Page hits during a 24-month period before the Prep Kit upload date vs mean Product Page hits during a 24-month period after the Prep Kit upload date.
- All outcomes were segmented by approval type (NME vs non-NME) and organization type (Managed Care, Pharmacy Benefit Manager (PBM), Government, Provider, Other).
  - Organizations in the "Other" category included academia and consultant.

RESULTS

PRODUCT AND HCDM CHARACTERISTICS

- A total of 82 products met the inclusion criteria.
  - Products were evenly distributed by approval type: 41 products (50.0%) were NMEs and 41 products (50.0%) were non-NMEs.
  - The sample included 24 hematology products (29.2%), 17 oncology products (20.7%), 22 CNS products (26.8%), and 19 immunology products (23.2%).
- A total of 696 unique users engaged with ≥1 hematology, oncology, CNS, or immunology product on the FD platform that was approved during 2018 and 2019.
  - The majority (44.1%) of users were managed care decision makers, followed by providers (21.6%) and PBM decision makers (19.1%) (**Figure 1**).
  - 471 users were pharmacists (74.1%), 79 (12.5%) held a position at the executive/director level, and 56 (8.8%) were a manager or supervisor.

TIME TO INITIAL HCDM ENGAGEMENT

- On average, HCDMs added products to their Watch List and requested a dossier 8.0 (SD=7.11) and 8.6 (SD=7.34) months prior to FDA approval, respectively. The mean time to first Product Page hit and Prep Kit hit was 6.8 (SD=6.55) and 2.7 (SD=2.01) months prior to FDA approval, respectively (**Figure 2**).
- Time to initial HCDM engagement was similar for NMEs and non-NMEs for all HCDM activity metrics.
- Across the majority of HCDM activity metrics, users in the "Other" category and government organizations engaged with the platform earlier relative to FDA approval compared to those in the provider, PBM, and managed care organization categories (**Figure 3**).

TRENDS IN HCDM ENGAGEMENT OVER TIME

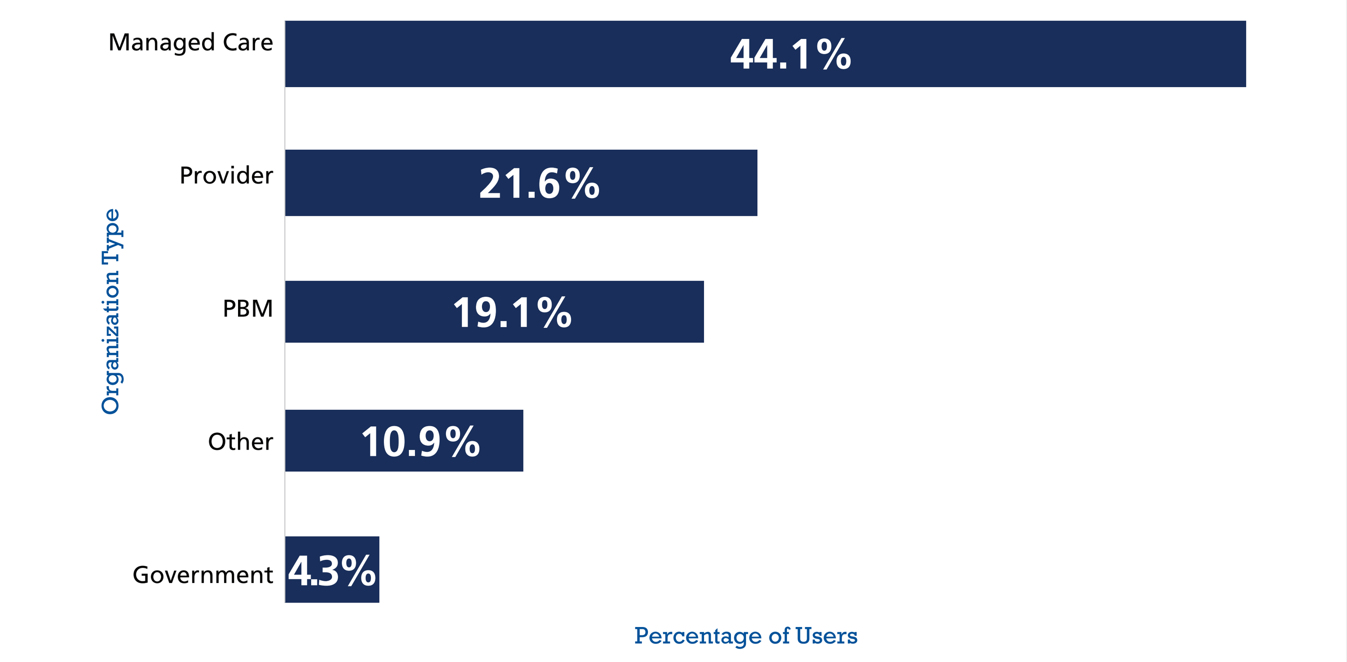
- Overall, there was an increase in HCDM engagement with the FD platform as time to FDA approval decreased regarding Product Page hits, Dossier Requests, and Prep Kit hits (**Figure 4**). Trends in HCDM engagement with Watch List adds were similar to that of Dossier Requests.

EFFECT OF PREP KIT UPLOAD ON HCDM ENGAGEMENT

- The sum of Product Page hits more than doubled after a Prep Kit was uploaded (298 vs 112, respectively) (**Figure 5**).
- Results were similar when segmented by approval type and organization type.
  - For NME approvals, the sum of Product Page hits nearly doubled after a Prep Kit was made available (144 vs 74, respectively). For non-NME approvals, the sum of Product Page hits was 4 times greater after Prep Kit upload (154 vs 38, respectively).
  - The sum of Product Page hits increased after Prep Kit upload across managed care, PBM, provider, and other organizations, with the greatest increase in HCDM activity across PBM and managed care organizations.
    - The sum of Product Page hits was 4.5 times greater after Prep Kit upload across registered users from PBMs (100 vs 22, respectively) and 3.2 times greater across registered users from managed care organizations (134 vs 42, respectively).

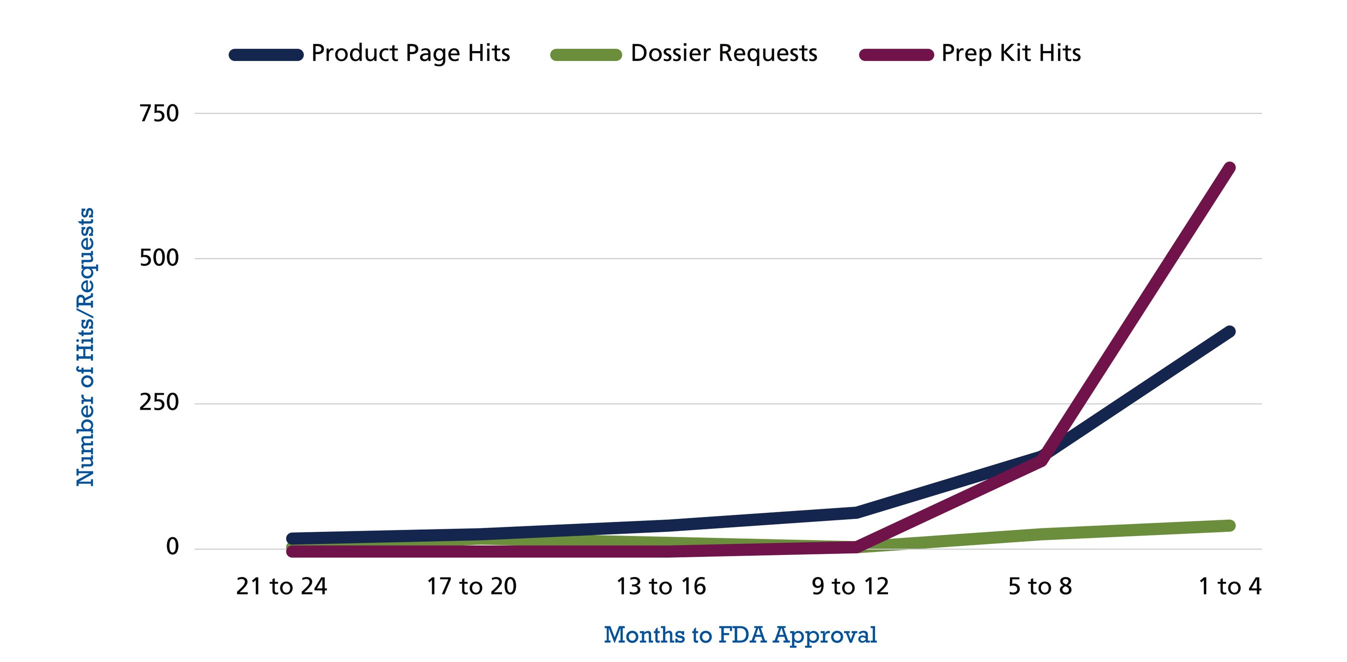
RESULTS (cont.)

Figure 1. FD Users by Organization Type



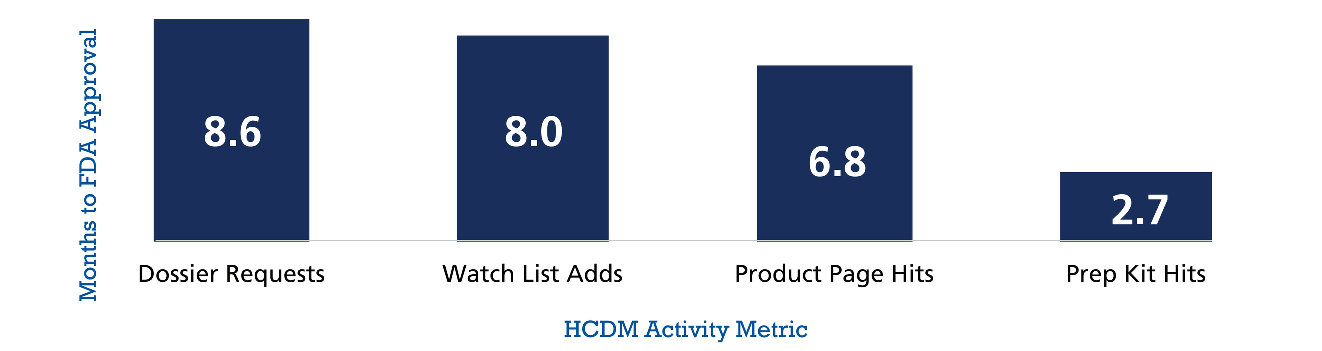
Key: FD - FormularyDecisions; PBM - pharmacy benefit manager.

Figure 4. Overall Tends in HCDM Engagement



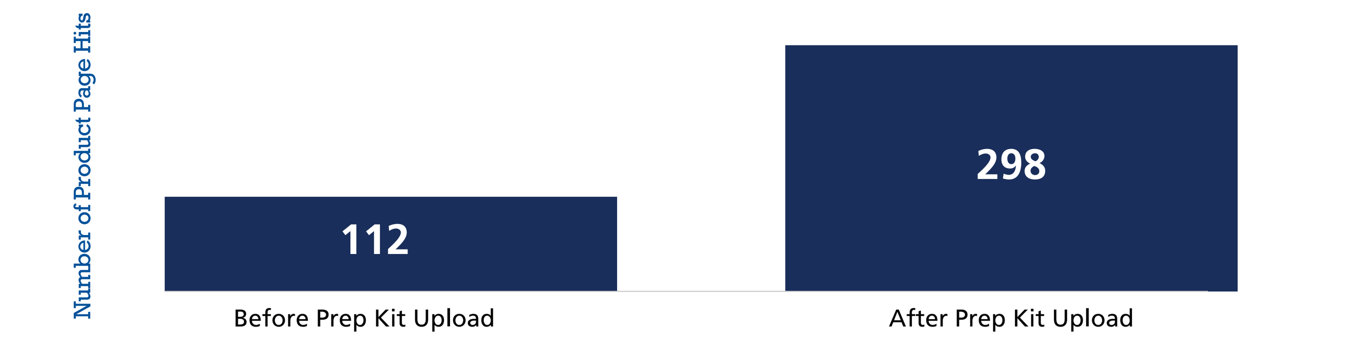
Key: FDA - Food and Drug Administration; HCDM - healthcare decision maker.

Figure 2. Mean Time to Initial HCDM Engagement



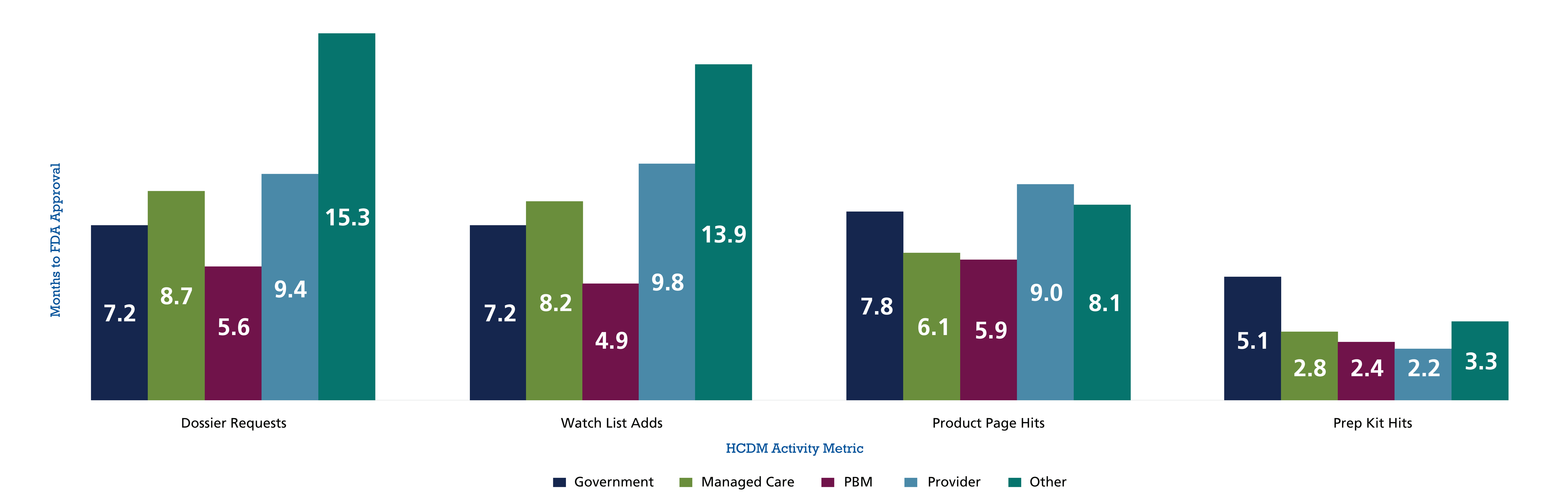
Key: FDA - Food and Drug Administration; HCDM - healthcare decision maker.

Figure 5. Overall Effect of Prep Kit Upload on HCDM Engagement



Key: HCDM - healthcare decision maker.

Figure 3. Mean Time to Initial HCDM Engagement by Organization Type



Key: FDA - Food and Drug Administration; HCDM - healthcare decision maker; PBM - pharmacy benefit manager.

LIMITATIONS

- This analysis focused on drugs that were FDA approved in 2018 and 2019 with HCDM activity available on the FD platform and reviewed only the activity that occurred 24 months prior to approval. The FDA and AMCP guidances were published in June 2018 and January 2020, respectively. Future evaluation may consider the inclusion of drugs beyond this criteria to evaluate potential HCDM engagement pattern differences following availability and increased familiarity with these guidances.
- At the time of analysis FD platform metrics were not provided at the indication-level; therefore HCDM activity related to a non-NME product (ie, approved product with supplemental indication) may not be associated with the new indication for which it was approved in 2018 to 2019.
- The low number of HCDMs in certain organization types may have led to more biased frequencies and means for activity indices; however, this corresponds to the demographics of organization types and user profiles of those registered HCDMs and of the FD platform overall.
- HCDM engagement with pre-approval information outside of the FD platform is not reflected in this analysis.

CONCLUSIONS

KEY FINDINGS

- HCDM activity on the FD platform increased after pre-approval information became available, regardless of the product's approval type and user's organization type (with the exception of government organizations).
- HCDMs within all organization types seek product information well in advance of FDA approval (as early as 24 months), and HCDM engagement trends upward as the approval date nears.
- NMEs often prompted greater HCDM interest than non-NMEs in the 24 months prior to FDA approval.
- HCDMs demonstrated greater activity with Prep Kits vs dossiers prior to FDA approval. This pattern is attributed to the lack of availability of dossier content during the analysis time period. Further research is required to clarify timing as the availability of pre-approval dossiers increases.
- Time to initial HCDM interest in pre-approval information and trends in HCDM engagement over time varied across organization types.

IMPLICATIONS

- There is an opportunity to support the increased exchange of pre-approval information between drug manufacturers and HCDMs via the FD platform.
- Manufacturers can support HCDM awareness and activity for their product prior to FDA approval by providing relevant information on the FD platform via Prep Kits and eDossiers, as well as other means of information exchange available on the FD platform.
- Manufacturers may consider initiating an exchange of pre-approval product information with HCDMs earlier prior to FDA approval.
- In addition, manufacturers should consider a customized approach to PIE with communication tools not only tailored to product approval type and customer organization type but also considering the overall strategy for the product.
- As PIE continues to evolve, further research should address potential shifts in HCDM pre-approval information utilization and types of PIE.

REFERENCES

1. Food and Drug Administration. Drug and device manufacturer communications with payors, formulary committees, and similar entities – questions and answers. Guidance for industry and review staff. https://www.fda.gov/media/102683/download. June 2018. Accessed February 24, 2020.
2. Academy of Managed Care Pharmacy. AMCP format for formulary submissions – guidance on submission of pre-approval and post-approval clinical and economic information and evidence, version 4.1. https://www.amcp.org/sites/default/files/2019-12/AMCP_Format%204.1_1219_final.pdf. Accessed February 24, 2020.

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Please direct questions to:
Minha Choi | Minha.Choi@xcenda.com