Industry Update

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AMDM 2022 IVD Focus Meeting

Agenda

- Key Developments in the last year
- Industry-wide trends
- Looking ahead to 2023 and beyond

Key Developments

- Important IVD-specific draft and final guidance documents
  - Reagent Replacement Policy (Aug. 2022)
- Also several Center-wide guidances
  - Final Clinical Decision Support Software (September 2022)
  - Draft Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (April 2022)
  - Draft Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry (April 2022)
- Rules
  - Final De Novo Rule (October 2021)
  - Proposed ISO 13485 Harmonization

Key Developments

- eSTAR
  - New electronic submission template will become mandatory October 1, 2023
- Customer Collaboration Portal
  - Upload all pre-market submission types to FDA electronically
  - End of pilot: as of October 2022, anyone can request access
- LDT Policy Update (Nov. 2021)
  - Withdrawal of policy that prevented LDT regulation without notice and comment rulemaking

Key Developments

- NIPT Warning to Patients & Providers (Apr. 2022)
  - Warning regarding potential for false results
  - While widely used, the letter notes that none have been cleared/approved
  - No actual evidence presented to support the warning
  - Interesting timing:
    - Comes after a January 2022 NY Times article regarding potential for erroneous results
    - Discussions of VALID and MDUFA are happening

- Notable FDA “enforcement actions”
  - Largely still focused on COVID (e.g., W.H.P.M. in June 2022 and Lusys Laboratories Feb. 2022)
  - Owlet (Oct. 2021)

Trends

- Notable Increase in IHTOA Letters
  - Across all Offices, but notably in OHT7
  - Topics include research use only (RUO), collection devices, among others
  - Emphasizes the importance of knowing the regulatory status of your devices/components and being able to file quickly if needed

Trends

- Expect Continued Delays
  - Still seeing delays across all submission types (e.g., pre-submissions, 510(k)s)
  - Pre-submission meetings with OHT7 are rare – very frequently being converted to written feedback only, including for “priority” device types (e.g., breakthrough devices)

- Escalations and Appeals
  - When does it make sense to involve management?
  - Don’t be afraid to push back when needed

Looking Ahead

- End of the COVID-19 Public Health Emergency
  - Draft guidance with transition plan issued in December 2021
  - No official transition date issued (yet)
  - End to automatic extension of AI response timing

- MDUFA V
  - No significant changes to 510(k) or PMA performance goals
  - Increase in performance goal for *de novos* 70% within 150 days (or 80% if fee increase)
  - Cap on number of pre-submissions subject to the user fee goal of 70 day

Looking Ahead

- Promotion and FDA enforcement action
  - Possible continued increase in IHTOA letters
    - Corresponding increase in Warning Letters?
  - Potential for increase in enforcement related to LDTs (e.g., collection devices) if VALID not passed
  - Keep an eye on competitors
  - FDA is taking some action, but it appears to be non-public (e.g., untitled letters)
  - Also consider other Agencies (e.g., Customs, FTC)

Questions & Discussion

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