Pharmacovigilance and Medication Error Reporting Systems:

Overview of FDA's Pharmacovigilance and Medication Error Reporting Systems

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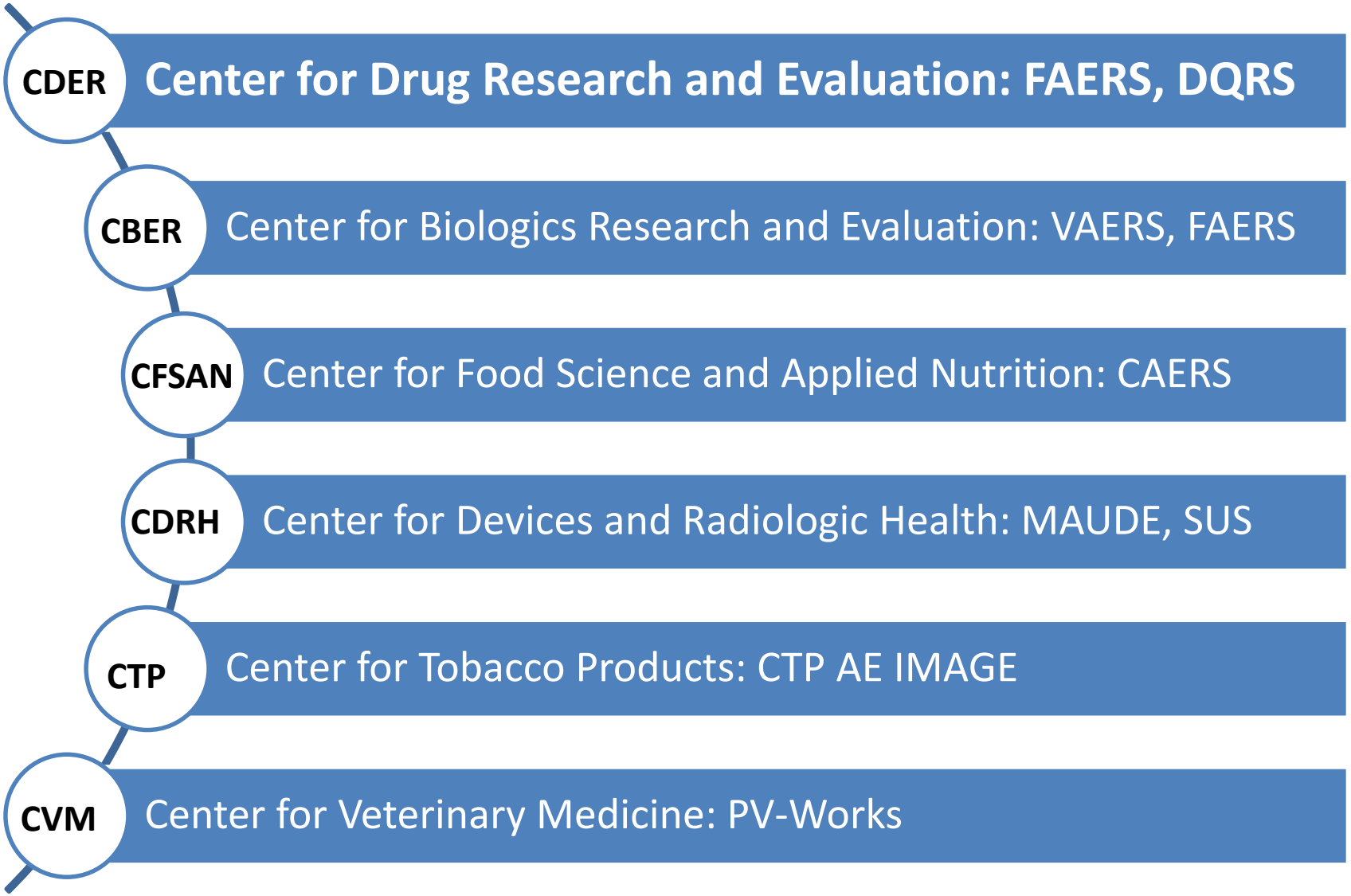
Medication Errors are a Global Public Health Burden

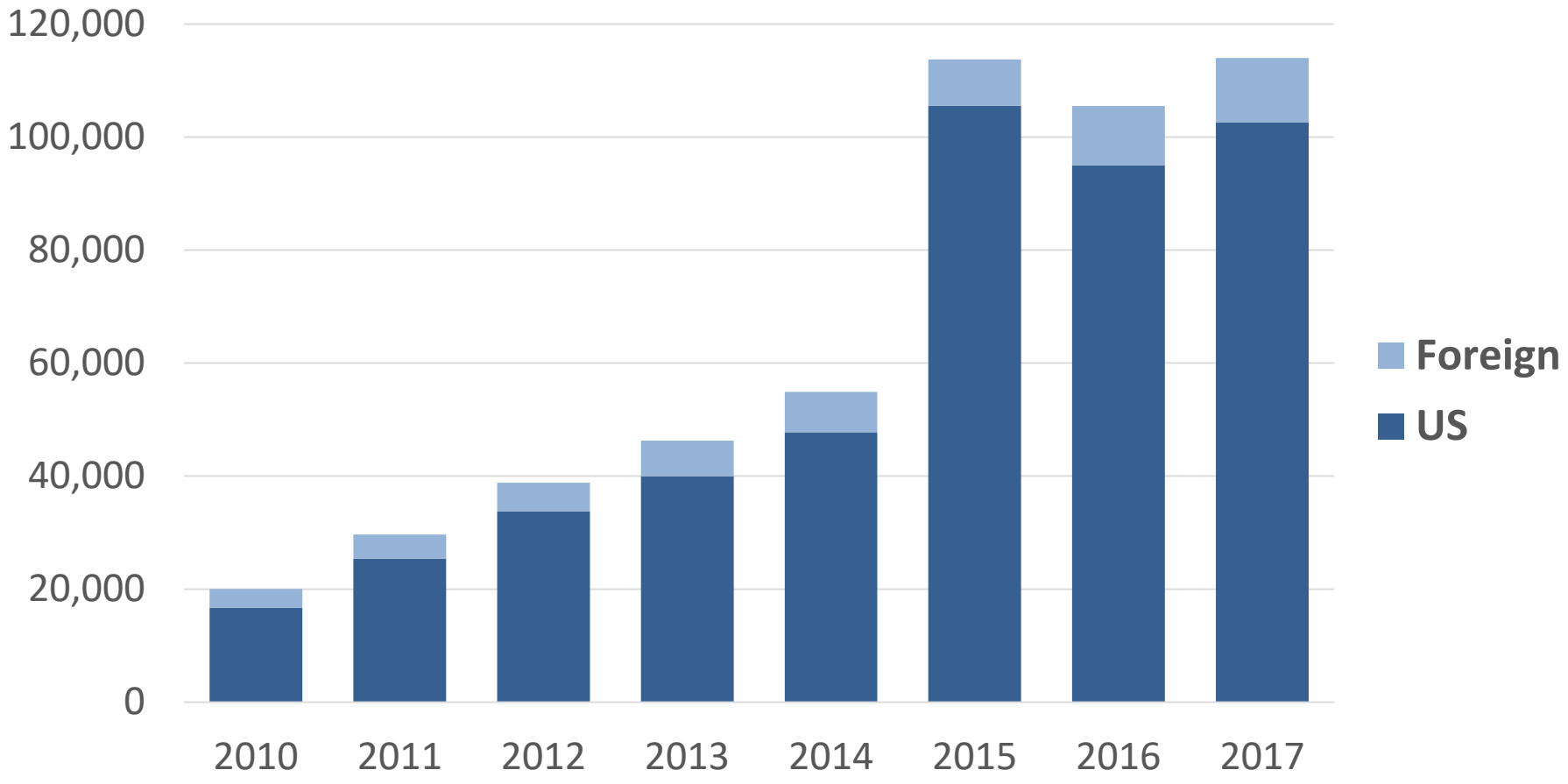
FDA Centers and Reporting Systems



Division of Medication Error Prevention and Analysis (DMEPA)

- Located within CDER (Center for Drug Research and Evaluation)
- Dedicated solely to medication error prevention and analysis for drug products
- Perform premarket reviews and postmarket pharmacovigilance for assigned drug products
- Use FAERS (FDA Adverse Event Reporting System) as primary source for postmarket monitoring of medication errors

Medication Error Reports in FAERS*



*Based on the MedDRA SMQ *Medication errors (narrow)*, V21

Medication Error Signal Detection and Analysis

- Focus on US FAERS reports (non-US products may have different labeling, practice settings, etc.)
- Form partnerships with patient safety organizations, USP, and other drug safety stakeholders
- Host teleconferences and collaborate with other regulatory agencies and FDA Centers
- Review periodic safety reports submitted by industry
- Evaluate and implement tools to use machine learning technology, predictive analytics, and other data sources

Challenges With Medication Error Pharmacovigilance

- ✓ Different medication error terminology, reporting requirements, labeling and product design, clinical practices
- ✓ Incomplete reports/lack of reporting forms tailored to capture medication error information
- ✓ Accurate product identification
  - Nomenclature (e.g., acetaminophen vs paracetamol, biosimilar suffixes)
  - Products with the same proprietary name but different ingredients
- ✓ Inconsistent and ambiguous coding of medication errors
- ✓ Identifying and reviewing labeling from other countries
- ✓ Timely sharing of information

Conclusion

- Medication errors are a global public health burden
- There is a need for harmonization, especially in the areas of:
  - Reporting (to capture relevant information)
  - Product identification
  - Medication error terminology and coding
- The timely sharing of information is imperative for medication error prevention and analysis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