Demonstration of FDA Databases and Publicly Available Tools

ORA/CDRH Resources Available to the Medical Device Industry

MEDCON 2023

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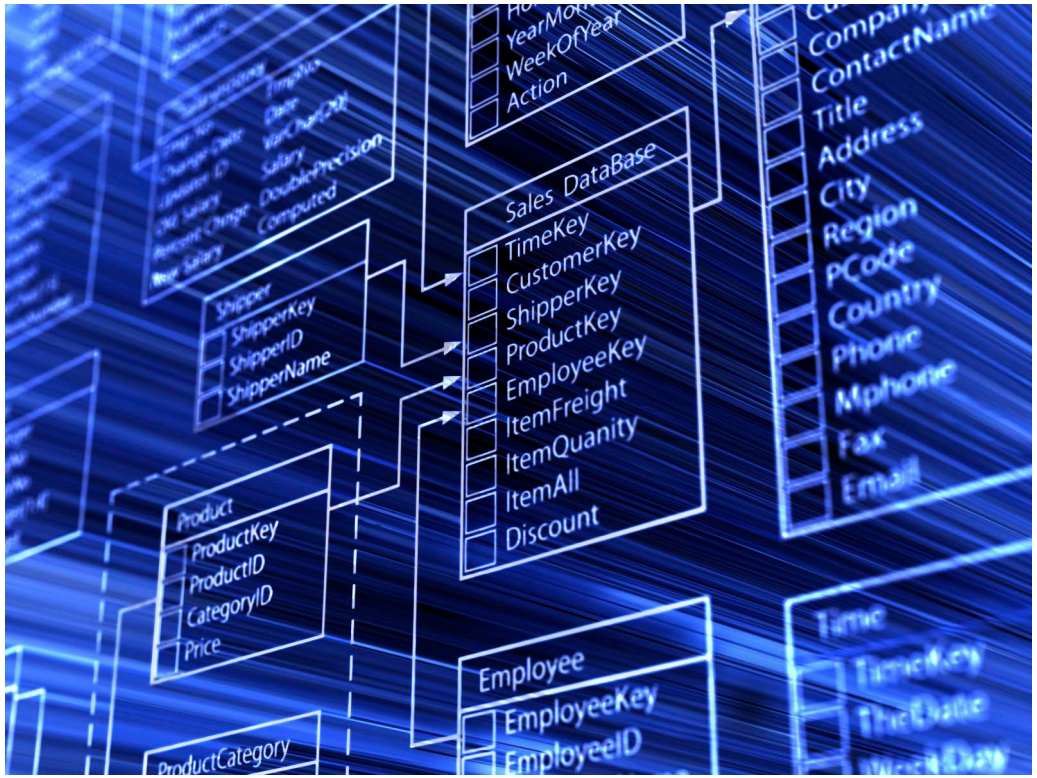
SUMMARY

FDA makes a large amount of information and data available to the medical device industry!

- Why does FDA make this data available?
- What data does FDA make available?
- How can I obtain this data?
- Where can I go to get my questions answered?



WHY DOES FDA MAKE THIS DATA AVAILABLE?

Presidential Memorandums and Directives

- Memorandum on Transparency and Open Government 01/21/2009
  - Push for information transparency
  - Disclose information rapidly in form easy to use
  - Leverage new technologies
  - Open Government Directive from OMB included online, open format, and openness as permitted by law
- Memorandum on Regulatory Compliance 01/18/2011
  - Make regulatory compliance and enforcement activities accessible, downloadable, and searchable online.

FDA's Transparency Initiative

- FDA launched a Transparency Initiative in June 2009
  - Phase I (01/2010)– *FDA Basics*
  - Phase II (05/2010) - *Public Disclosure*
  - Phase III (01/2011) – *Transparency to Regulated Industry*
- Additional efforts and reporting:
  - Report on Good Guidance Practices (12/2011)
  - Transparency Reports on Compliance and Enforcement Activity (10/2011, 01/2012, 04/2014)
  - CDRH Transparency activities (e.g. TPLC)

WHAT DATA DOES FDA MAKE AVAILABLE?

Data Types

- Premarket Data
  - 510(k) Premarket Notifications
  - Premarket Approvals (PMA)
  - De Novo 513(f)(2) Classifications
- Post-market Data
  - Medical Device Reports (MAUDE)
  - Recalls
  - Radiation Emitting Electronic Products Corrective Actions
- Firm/Device Data
  - Registration/Listing
  - Device Classification
  - Total Product Lifecycle (TPLC)
  - UDI Coding
- Regulatory Activity Data
  - Inspections
  - 483 Observations (Citations)
  - Compliance Actions

Quantity of Data

- Device Classifications (~6,700)
- Registration and listing data for medical device firms and their products (~300,000)
- Premarket Approvals (PMAs) and supplements (~47,000)
- 510(k) Clearances (~160,000)
- Recalls (~46,000)
- Adverse event reports (~14 million)
- UDI Coding (~3,000,000)

Limitations

- Routinely publish only certain types of data – not all FDA data
- Certain delays before publishing (e.g. final classification)
- Does not include data restricted from disclosure
- Data should be treated as unvalidated – many data sets include user-submitted and/or manually entered data

HOW CAN I OBTAIN THIS DATA?

Methods – Web Search

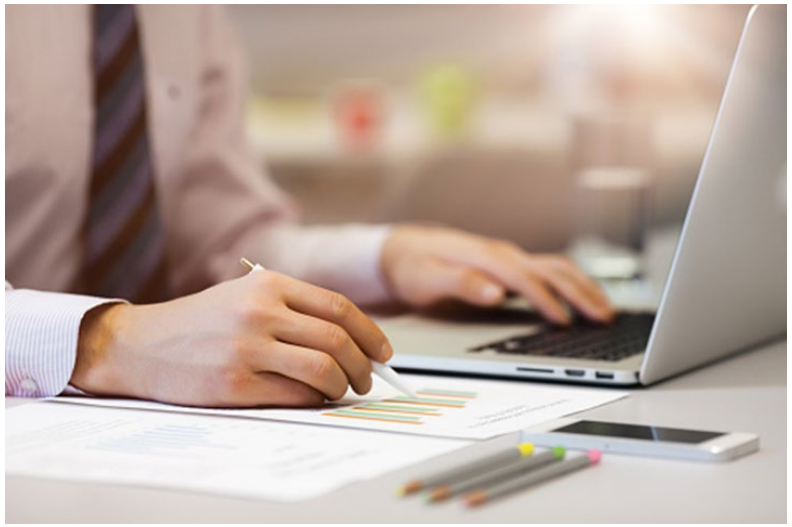
- **Web searches of databases/dashboards on FDA.gov**
  - Search can be tailored easily using criteria, requires only a web browser
  - Many results include links to other resources
  - Formatting prioritized for human readability and use, including some graphical representations of the data
  - Some allow all or a portion of the data to then be exported for review in other applications

Methods – Downloads & API

- **Download entire datasets**
  - Different formats/processes depending on source, may require certain applications to view properly
  - Larger datasets are broken into more than one file, may require manual or automated combination to make data usable
- **Application Programming Interface (API) calls**
  - Scope of query can be tailored to needs/interest
  - Formatting prioritized for use by applications
  - Requires some knowledge to properly structure and submit requests

Deciding on a Method

- What type of data are you looking for?
  - Some data sets can be searched using multiple methods



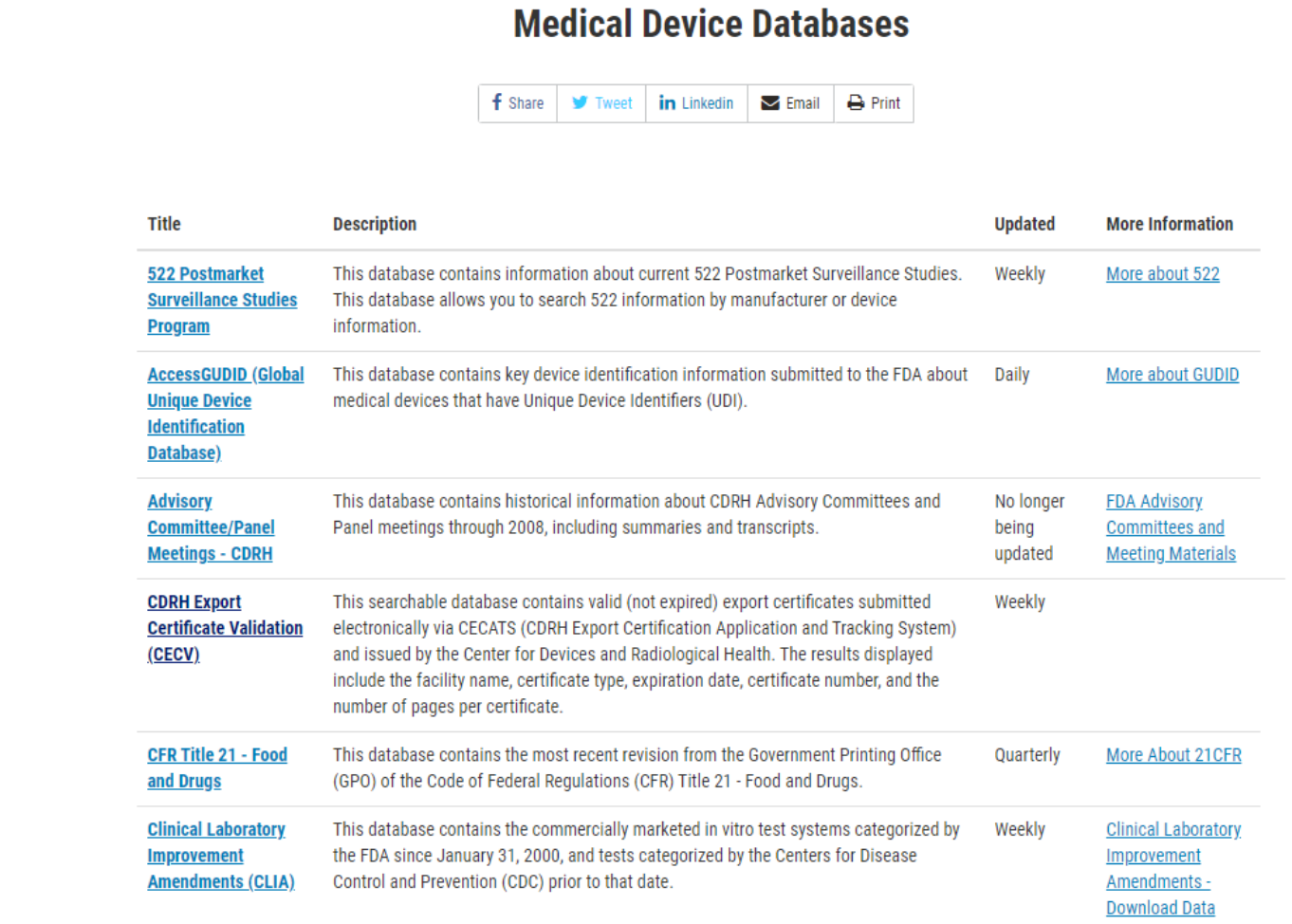
- Are you looking to return a small or large number of results?
- How complex of a query do you need to get the data you want?
- What will you be doing with the data once you obtain it?

Example JSON Return


```
  "results": [
    {
      "cfres_id": "173284",
      "product_res_number": "Z-0053-2020",
      "event_date_initiated": "2019-05-17",
      "event_date_created": "2019-10-07",
      "recall_status": "Terminated",
      "event_date_terminated": "2020-09-24",
      "res_event_number": "82984",
      "product_code": "FOZ",
      "k_numbers": [
        "K900263"
      ],
      "product_description": "Pediatric Two-Lumen Central Venous
Catheterization\nKit with Blue FlexTip ARROWg+ard Blue Catheter, REF AK-
25502\n\nProduct Usage;  Provide short-term (< 30 days) central venous access
for treatment of diseases or conditions requiring central venous access",
      "code_info": "Lot/Batch Numbers: 13F18C0374, 13F18H0580, 13F18D0504,
13F18L0507,  13F18E0380, 13F18L0714, 13F18G0180, 13F18L0936,  13F18G0480",
      "recalling_firm": "Arrow International Inc",
```

Medical Device Databases

The list of Medical Device Databases is found at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases



Medical Device Databases

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Title	Description	Updated	More Information
522 Postmarket Surveillance Studies Program	This database contains information about current 522 Postmarket Surveillance Studies. This database allows you to search 522 information by manufacturer or device information.	Weekly	More about 522
AccessGUDID (Global Unique Device Identification Database)	This database contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).	Daily	More about GUDID
Advisory Committee/Panel Meetings - CDRH	This database contains historical information about CDRH Advisory Committees and Panel meetings through 2008, including summaries and transcripts.	No longer being updated	FDA Advisory Committees and Meeting Materials
CDRH Export Certificate Validation (CECV)	This searchable database contains valid (not expired) export certificates submitted electronically via CECATS (CDRH Export Certification Application and Tracking System) and issued by the Center for Devices and Radiological Health. The results displayed include the facility name, certificate type, expiration date, certificate number, and the number of pages per certificate.	Weekly	
CFR Title 21 - Food and Drugs	This database contains the most recent revision from the Government Printing Office (GPO) of the Code of Federal Regulations (CFR) Title 21 - Food and Drugs.	Quarterly	More About 21CFR
Clinical Laboratory Improvement Amendments (CLIA)	This database contains the commercially marketed in vitro test systems categorized by the FDA since January 31, 2000, and tests categorized by the Centers for Disease Control and Prevention (CDC) prior to that date.	Weekly	Clinical Laboratory Improvement Amendments - Download Data

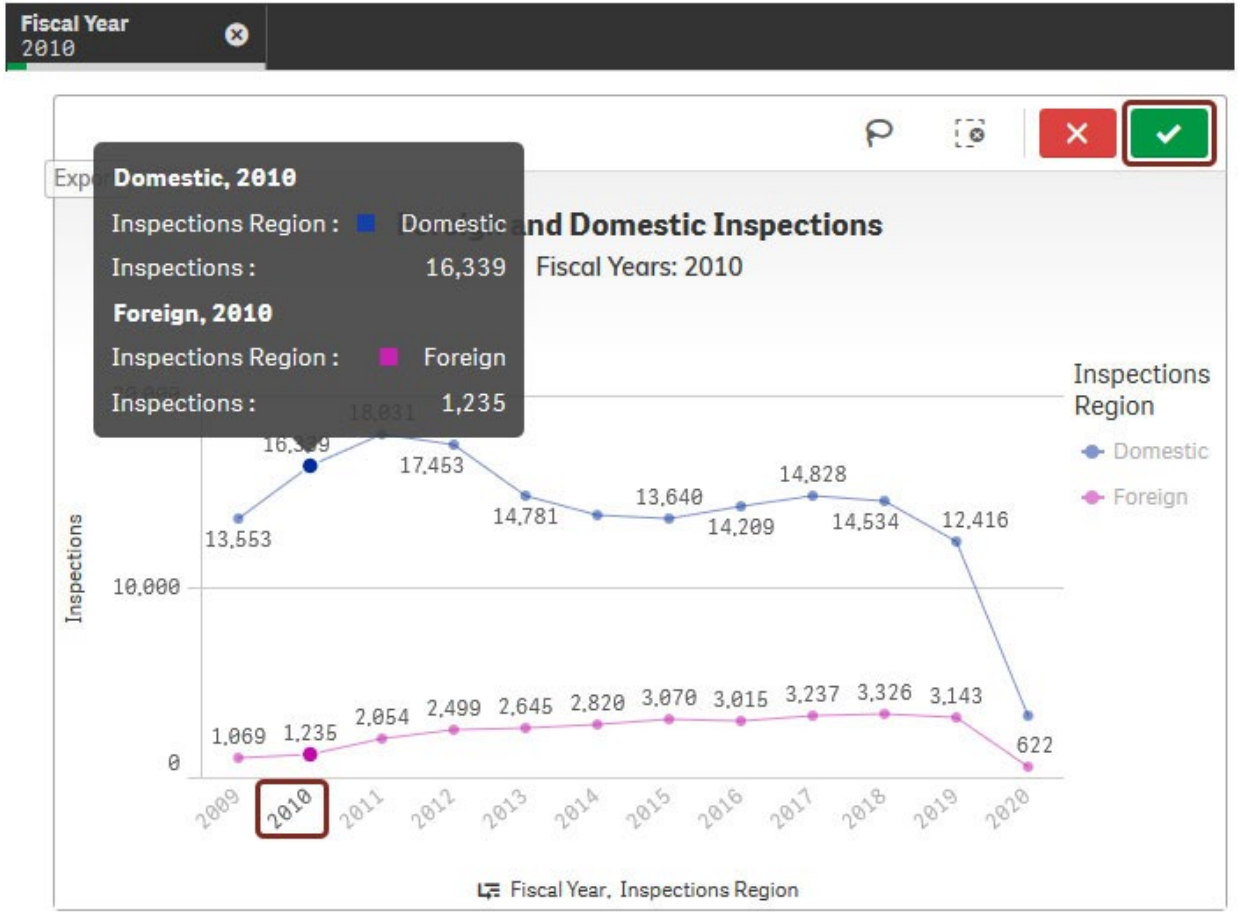
Medical Device Databases Cont.

- Includes Premarket, Post-Market, and Firm/Device Data
- Links to resources about the data set and compliance requirements
- Many offer export to CSV for complete dataset or search results

- DEMONSTRATION:
  - Device Classification
  - 510(k)
  - MAUDE
  - Total Product Life Cycle (TPLC)

Medical Device Databases Demo

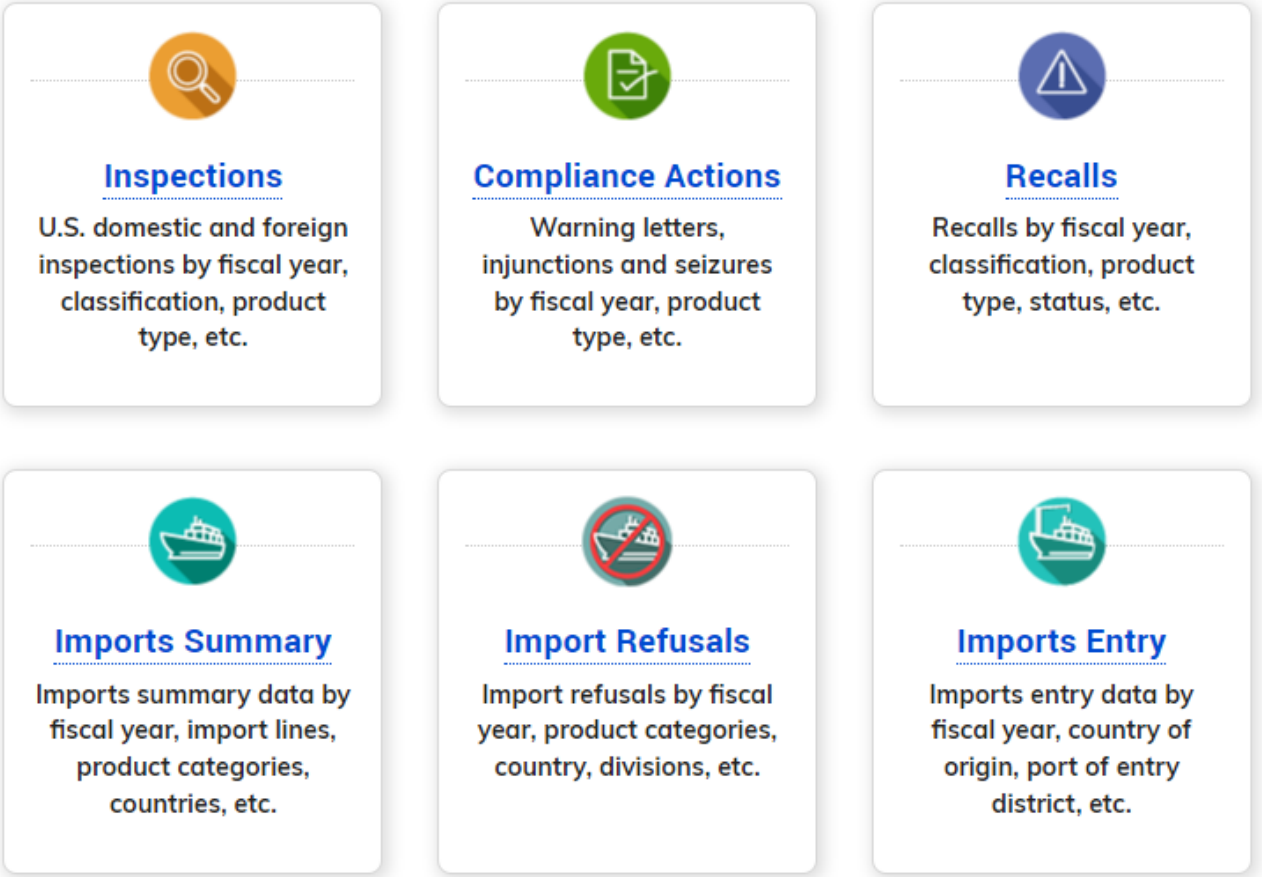
Data Dashboards



- Released in 2014, afford access to variety of compliance data
- Allow visualization of data in charts/graphs
- Updated over time to add additional data types

Compliance Data Dashboards

- Compliance Data Dashboards found here: https://datadashboard.fda.gov/ora/cd/index.htm



Compliance Data Dashboards Cont.

- Dashboards include charts and tables displaying data
- Filters and searching available to help visualize data of interest
- Can download either full dataset, or a subset based on your filters (XLSX format with column headers)

- DEMONSTRATION
  - Inspections/Citations
  - Compliance Actions
  - Recalls

Data Dashboard Demo

OpenFDA

- Released in 2014 to make it easier for FDA regulatory stakeholders to obtain important datasets
- Can download complete datasets, or have programs query via Application Programming Interfaces (APIs)

OpenFDA Download

- The link to download data sets is here: https://open.fda.gov/data/downloads/
- Data in zipped JSON format by endpoint, some may have many files due to size
- A Data Dictionary which defines each of the field names present in the data is provided here: https://open.fda.gov/data/datadictionary

- DEMONSTRATION
  - Recalls

OpenFDA Recalls Data Demo

Data Dashboard and OpenFDA APIs

- Allows using structured queries to the server to return information of interest in JSON format
- FDA Data Dashboard https://datadashboard.fda.gov/ora/api/index.htm
- OpenFDA https://open.fda.gov/apis/
- Over 16 million API calls to OpenFDA in last 30 days!


```
{
    "start" : 1,
    "rows" : 10,
    "sort" : "ProductCode",
    "sortorder" : "ASC",
    "filters" : {
        "FEINumber":[3003378587,1000117386,3008091479]
    },
    "columns" : [
        "FEINumber",
        "FirmName",
        "CountryCode",
        "ProductCode",
        "RefusalDate"
    ]
}
```

WHERE CAN I GO TO GET MY QUESTIONS ANSWERED?

Device Resources

- CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn) provides training on basic FDA regulatory requirements related to the development, manufacture, and distribution of medical devices. Topics include:
  - Basics
  - How to Study and Market Your Device
  - Post-market Activities
  - Unique Device Identification (UDI) System
  - Specialty Technical Topics

Division of Industry and Consumer Education (DICE)

- Contact for regulatory questions from firms and the public, and develops educational resources to help industry understand FDA regulations and policies
- Will respond to question within 3-4 days

Email: DICE@fda.hhs.gov

Phone: 1(800) 638-2041 or (301) 796-7100

9AM-12:30PM, 1:00PM-4:30PM ET

RECAP

FDA makes a large amount of information and data available to the medical device industry!

You should now know:

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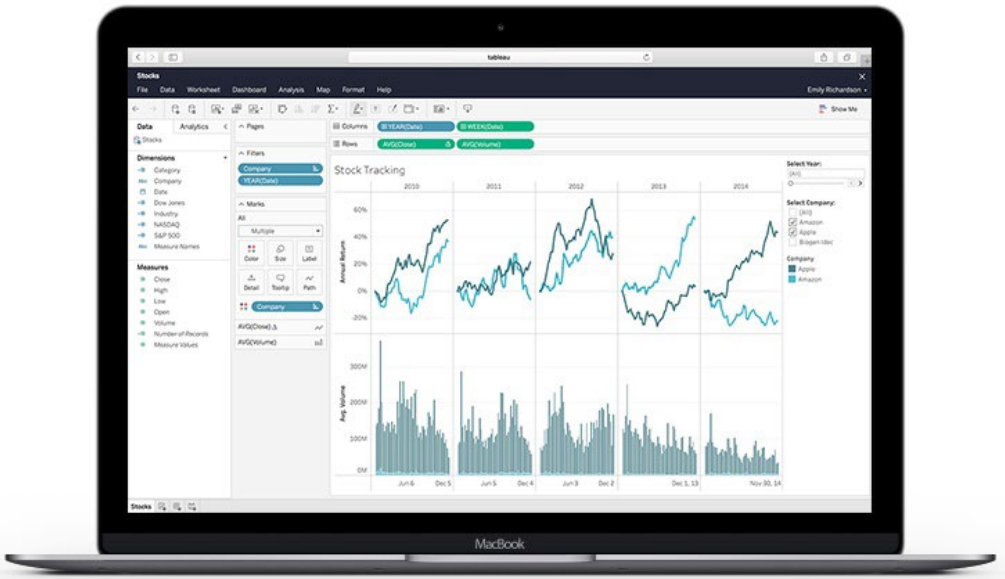

QUESTIONS?

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