The purpose of this article is to describe the complexity of FDA recall data sources and when to use which source

Take-aways:

- if you want to track how many recall devices (how many ventilators have been recalled), use recall datasets
- if you want to track recall process (ongoing, complete, terminated), use enforcement reports

There are 8 (or more) sources to pull recall data

Recall:

1. Recall news: https://www.fda.gov/medical-devices/medical-device-recalls/2020-medical-device-recalls
2. Recall web search: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm
3. Recall API: https://open.fda.gov/apis/device/recall/
4. Recall dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm

Enforcement:

1. Enforcement weekly reports: https://www.accessdata.fda.gov/scripts/ires/index.cfm
2. Enforcement web search: https://www.accessdata.fda.gov/scripts/ires/index.cfm
3. Enforcement API: https://open.fda.gov/apis/device/enforcement/
4. Enforcement weekly API: https://www.accessdata.fda.gov/scripts/ires/apidocs/

Different definition between Recall vs Enforcement

"A **recall** is an action taken to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health."

Enforcement serves the purpose of tracking recall process (firm initiated recall, recall was classified, recall was reported to public, recall was terminated) "All recalls monitored by FDA are included in the Enforcement Report once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Once FDA completes the hazard assessment, the Enforcement Report entry will be updated with the recall classification."

Different search results for the same keyword using different search engines

	Recall dashboard	Recall web search	Recall API
columns available	['FEI Number', 'Recalling Firm Name', 'Product Type', 'Product Classification', **'Status'**, 'Distribution Pattern', 'Recalling Firm City', 'Recalling Firm State', 'Recalling Firm Country', 'Center Classification Date', 'Reason for Recall', 'Product Description', 'Event ID', 'Event Classification', 'Product ID', 'Center', 'Firm Profile', 'Recall Details']	WEB_ADDRESS, RECALL_NUMBER, PRODUCT_DESCRIPTION, **TRADE_NAME**, RECALL_CLASS, CENTER_CLASSIFICATION_DT, **POSTED_INTERNET_DT, TERMINATION_DT,** FIRM_NAME, MANUFACTURER_RECALL_REASON	['res_event_number', 'firm_fei_number', 'k_numbers', 'pma_numbers', 'device_name', 'medical_specialty', 'device_class', 'product_code', 'root_cause_description', **'event_date_terminated',** 'product_res_number']
Pros and cons of each search engine	pros: 'status' column, able to track recall process cons: don't have a specific column for trade name —> need to clean/extract trade name in free text 'Product Description' column	pros: able to search for specific trade name within a time range cons: not return a complete search, only limit to 500 results for 1 single search	pros: can search for a more general device name (ventilator, pump), return a highest search result cons: doesn't have any columns for specific brand name —> pretty much useless
When to use	track recall process, data was from the same source as Enforcement Report	quick search with specific brand name (search result downloadable)	use as an upper limit of search result
keyword 'anesthesia'	188 results	482 results	754 results
keyword 'dialysis'	299 results	> 500 results	675 results
keyword 'pump'	547 results	> 500 results	2043 results
keyword 'ventilator'	138 results	325 results	629 results
k_number = 'K131252'		6 results (1 result with no termination date)	10 results (2 results with no termination date)

Why there is a big gap in search results between recall dashboard and the other 2 search engines? probably because they are from different sources, since the dashboard has 'status' column, which is closer to the Enforcement Report than the other 2 methods.

Why there are a huge difference in search results between Recall web search and Recall API?

Recall web search with 'k_number' = 'K131252':

WEB_ADD	RECALL_NUMBER	PRODUCT	TRADE_NAME	RECALL_C	CENTER	CENTER_CLASSI	POSTED_INTERNET_DT	TERMINATION_DT	FIRM_NAM	MANUFACTURER_RECALL_REASON
http://www..	Z-1208-2018	Rechargea	Puritan Bennett TM Ventilator System SE	2	CDRH	2018/03/27			Covidien LL	Rechargeable lithium-ion batteries with incorrect firmware
http://www..	Z-1181-2016	Puritan Ber	Puritan Bennett 980 Ventilator System	2	CDRH	2016/03/16	2016/03/17 21:00:07	2017/07/11	Covidien LP	Graphical user interface (GUI) unresponsive to touch and
http://www..	Z-2329-2015	Puritan Ber	Puritan Bennett 980 Ventilator System U	1	CDRH	2015/08/14	2015/08/14 21:00:16	2016/06/02	Covidien LP	Reports in which tidal volumes reaching patients were lo
http://www..	Z-1058-2015	Puritan Ber	Puritan Bennett 980 Ventilator System	2	CDRH	2015/02/05	2015/02/05 21:00:19	2016/01/06	Covidien LP	Covidien is issuing a voluntary field action for all Puritan B
http://www..	Z-0180-2015	Covidien Pi	Puritan Bennett	1	CDRH	2014/12/09	2014/12/09 21:00:07	2016/07/01	Nellcor Pur	Covidien is recalling certain Puritan Bennett 980 Ventilator
http://www..	Z-0112-2015	Covidien Pi	Puritan Bennett	1	CDRH	2014/10/28	2014/10/28 21:00:04	2016/05/02	Nellcor Pur	A software issue may lead to ventilator inoperative situatio

Recall_API with 'k_number' = 'K131252'

res_event_n	firm_fei_number	k_numbers	pma_numbe	device_name	medical_spe	device_class	product_cod	root_cause_description	event_date_termin	product_res_number
79371	3013710866	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Process Control		Z-1208-2018
69320	2936999	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Software Design(Device)	5/2/16	Z-0112-2015
69320	3002807850	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Software Design(Device)	5/2/16	Z-0112-2015
73096	2936999	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Under Investigation by the Fir	7/11/17	Z-1181-2016
70239	2936999	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Software Design(Device)	1/6/16	Z-1058-2015
71675	2936999	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Software Design(Device)	6/2/16	Z-2329-2015
79371	1219930	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Process Control		Z-1208-2018
69324	3002807850	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Device Design	7/1/16	Z-0180-2015
71675	3002807850	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Software Design(Device)	6/2/16	Z-2329-2015
69324	2936999	['K131252']		Ventilator, Continuous, Facility Use	Anesthesiolo	2	CBK	Device Design	7/1/16	Z-0180-2015

In this recall_api, there are 4 duplicates in 'res_event_number', 'event_date_termination', and 'product_res_number', the only different is in **'firm_fei_number'.** If this logic applies to 1 single product (Puritan 980 ventilator with k_number = 'K131252'), it can explain why there are a huge difference in search results between Recall web search and Recall API.

Recall dashboard example:

FEI Number	Recalling Firm Name	Product Type	Product Classification	Status	Distribution Pattern	Recalling Firm City	Recalling Firm State	Recalling Firm Country	Center Classification Date	Reason for Recall	Product Description	Event ID	Event Classification	Product ID	Center	Firm Profile	Recall Details
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180682	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180686	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180687	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180688	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180689	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180690	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
2025816	ICU Medical, Inc.	Devices	Class II	Ongoing	US Consignees	San Clemente	California	United States	05/14/2020	Inability for the guid	Central Venous Cath	85361	Class II	180691	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires
3009549	Access Scientific I	Devices	Class II	Ongoing	US Nationwide	San Diego	California	United States	05/14/2020	Saline Flush Syringe	BD PosiFlush SF Sali	85586	Class II	181295	CDRH	https://datada	https://www.accessdata.fda.gov/scripts/ires

Enforcement Reports data sources: openfda vs accessdata.fda.gov

openfda enforcement source: FDA Recall Enterprise System (RES) The Recall Enterprise System (RES) is an electronic data system used by FDA recall personnel to submit, update, classify, and terminate recalls.

event_id	recall_number	recall_initiat	center_classi	report_date	product_description	product_quantity	status	termination_date
81932	Z-0831-2019	20190122	20190214	20190220	COBRA FUSION 150 Ablation System, Catalog # (REF) 700-001S	175 units	Terminated	
81932	Z-0830-2019	20190122	20190214	20190220	COBRA FUSION 150 Ablation System, Catalog # (REF) 700-001	6176 units	Terminated	
81932	Z-0829-2019	20190122	20190214	20190220	COBRA FUSION 50, Ablation System, Catalog # (REF) 700-002	1288 units	Terminated	
81932	Z-0832-2019	20190122	20190214	20190220	COBRA FUSION 150 Ablation System (International Only), Catalog # (REF) 700-001MI	765 units	Terminated	
75373	Z-0653-2017	20160922	20161122	20161130	COBRA Fusion 50 Ablation System, COBRA Fusion 150 Ablation System, and COBRA Fusion Magnetic	5,263	Terminated	20180208