Pancreas Medical Device Recall

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Abstract

This study focuses on the crucial role of the pancreas in human health, emphasizing its endocrine and exocrine functions and the management of related disorders such as diabetes and pancreatic cancer. Our findings highlight the challenges in the reliability and safety of medical devices like insulin pumps and glucose monitoring systems, often necessary for disease management. We report frequent device recalls due to technical malfunctions and emphasize the need for stringent regulatory oversight and technological advancements in device design. The study underscores the importance of comprehensive patient education in enhancing device efficacy and patient safety. In conclusion, our research advocates for a multidisciplinary approach to improve the reliability and effectiveness of pancreatic medical devices, thereby enhancing patient care and treatment outcomes.

Keywords: *pancreas, medical device, medical device recall.*

Introduction

The pancreas serves as a critical organ in the human body with dual functionalities: endocrine and exocrine. Its endocrine function is instrumental in regulating blood glucose levels through the secretion of hormones such as insulin and glucagon, playing a significant role in diabetes management (American Diabetes Association, 2021). The exocrine aspect involves producing digestive enzymes essential for nutrient breakdown and absorption (Forsmark, 2017). Consequently, pancreatic disorders like diabetes, pancreatitis, and pancreatic cancer have profound health implications, necessitating effective medical interventions (Maitra & Goggins, 2020).

Medical devices that assist pancreatic functions, such as insulin pumps and continuous glucose monitoring systems, are pivotal in managing diabetes. Their reliability and accuracy are crucial since malfunctions can result in severe health risks like hypoglycemia or hyperglycemia (Klonoff, 2018). However, these devices have encountered issues leading to recalls due to software errors, hardware malfunctions, and inaccurate readings (Zhou et al., 2022; Smith et al., 2019).

The frequent recalls highlight the need for stringent regulatory oversight and thorough testing protocols (Zuckerman et al., 2011). The FDA plays a vital role in ensuring the safety and efficacy of these medical devices, with their post-market surveillance systems being crucial for monitoring device performance in real-world settings (Shuren & Califf, 2016).

Research in this field increasingly focuses on improving the design and functionality of pancreas-related medical devices. This includes sensor technology advancements, robust insulin delivery system algorithms, and user-friendly interfaces to minimize errors (Desai & Gross,

2018; Heinemann & Krinelke, 2012). Comprehensive patient education and training are also essential to ensure correct device usage, significantly reducing device-related errors and improving patient outcomes (Vallis, 2016; Polonsky & Hessler, 2015).

In summary, research on the pancreas and its related medical devices is vital for managing pancreatic diseases and advancing medical technology and patient safety. Continuous innovation, regulatory vigilance, and research are essential to enhance the reliability and efficacy of these life-sustaining devices.

The research into factors leading to the recall of pancreas medical devices is crucial for patient safety and healthcare quality. Medical errors, including device failures or design flaws, significantly impact patient outcomes and are a major cause of morbidity and mortality (Liebel et al., 2018). These failures can arise from various factors, such as design flaws, manufacturing errors, inadequate user training, or complications in clinical settings (Smith et al., 2019).

Regulatory reforms are necessary for medical device safety, including more stringent pre-market testing and robust post-market surveillance (Zuckerman et al., 2011; Shuren & Califf, 2016). Most device recalls are due to issues that could have been identified with more rigorous testing, emphasizing the need for comprehensive evaluation strategies (Kesselheim et al., 2011).

Patient education and psychological well-being are also critical in managing chronic conditions that require complex medical devices (Vallis, 2016). Additionally, technological advancements present both opportunities and challenges in developing safer and more effective medical devices (Desai & Gross, 2018; Heinemann & Krinelke, 2012).

In conclusion, enhancing patient safety and healthcare quality in relation to pancreas medical devices necessitates a multidisciplinary approach involving regulatory oversight, technological innovation, comprehensive patient education, and ongoing surveillance.

Understanding the causes behind these recalls is crucial for preventing future errors and improving device reliability and efficacy, particularly for life-sustaining devices like insulin pumps and glucose monitors (Ball et al., 2018). Device reliability directly affects patient well-being, with malfunctions leading to serious health consequences and impacting patient trust in medical technologies (McAdams et al., 2018; Vallis, 2016).

The recall process can be disruptive for patients, underscoring the need for rigorous pre-market testing and ongoing post-market surveillance (Hauser et al., 2010; Zuckerman et al., 2011). The FDA's role in ensuring device safety through approval processes and oversight is critical (Shuren & Califf, 2016). Effective patient education and training are key to mitigating risks associated with medical devices (Polonsky & Hessler, 2015).

In summary, addressing the factors leading to pancreas medical device recalls requires improved device design and testing, stringent regulatory oversight, effective patient education, and robust post-market surveillance. This approach is vital for enhancing patient safety, ensuring device reliability, and improving the quality of life for those dependent on medical devices.

Methedology

The information collected encompasses a variety of critical parameters, each contributing to the comprehensive analysis and understanding of a significant event. Among these pivotal data points are the total count of devices that have been subjected to recall. Additionally, the recall

date serves as a marker, allowing a detailed examination of the events leading up to the initiation of the recall.

Furthermore, the identity and role of the corporate entity responsible for the recall are integral components of the data collection process. This includes an exploration of the company's profile, standing within the industry, and any pertinent contextual information that may shed light on the motivations and circumstances surrounding the recall. Unveiling the corporate aspects contributes to a more comprehensive view with this recall initiative.

The distribution dynamics of the affected devices from another dimension of the data being amassed, encompassing a thorough examination of how these products have been disseminated across various markets and regions. This detailed analysis of devices' geographical and demographic reach is instrumental in gauging the potential impact on consumers and stakeholders, thereby adding depth to the overall understanding of the recall.

An additional layer of complexity arises from investigating the specific issues afflicting the recalled devices. This includes but is not limited to issues such as faulty design, software anomalies, and manufacturing irregularities. The detailed examination of each issue type provides valuable insights into the intricacies of the challenges faced, allowing for a nuanced understanding of the circumstances surrounding the recall and facilitating informed decision-making in devising remedial actions.

<div align="center">**Data Collection**</div>

The objective of this report is to detail the process of scraping FDA data from the official OpenFDA platform. OpenFDA, an Elasticsearch-based API, provides valuable public data about drugs, devices, and foods, including information on recalls, adverse events, and more. The primary goal of this data scraping project is to extract meaningful insights from the Device Recall dataset provided by the OpenFDA API.

Data Source

The data for this project is sourced from the OpenFDA API, an Elasticsearch-based platform that serves public FDA data about drugs, devices, and foods. The focus is on the Device Recall dataset. The following figure displays different breaches of data underneath the big umbrella of FDA
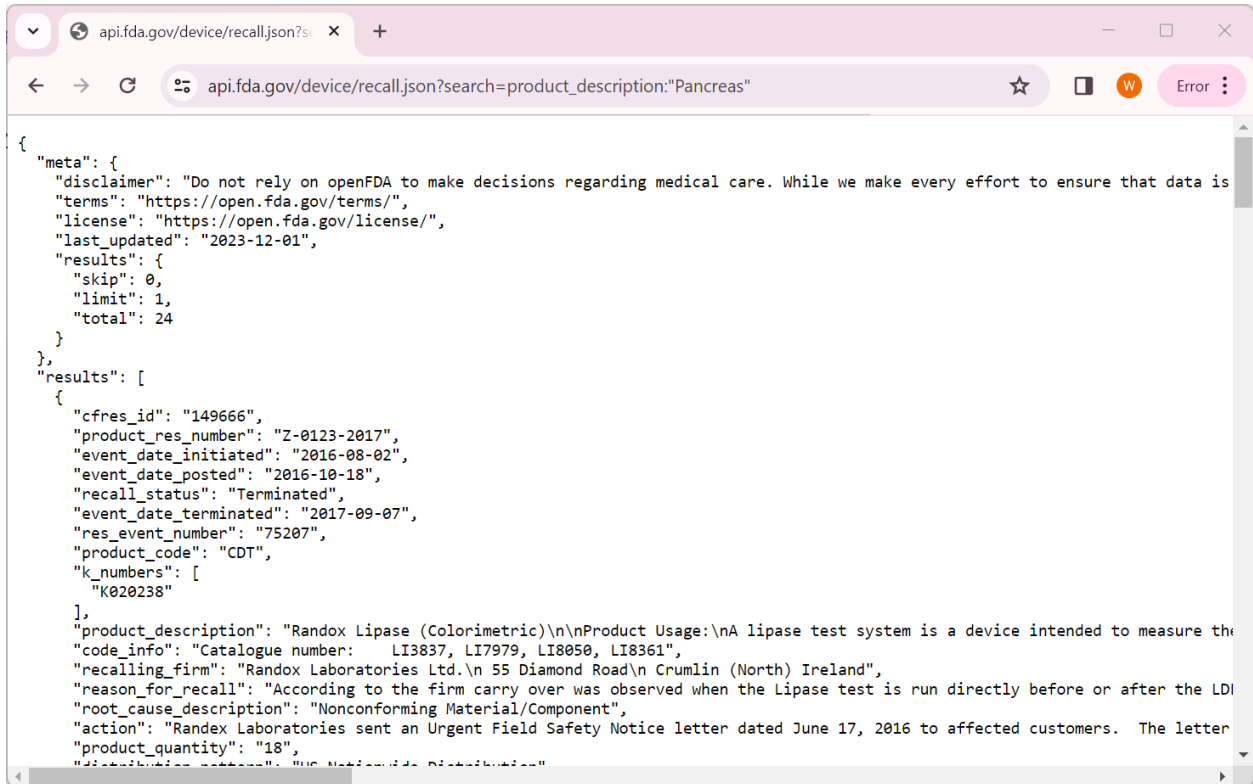
Scraping Process

  The tools and technologies employed for scraping include Python for programmatically sending requests, and libraries such as BeautifulSoup and requests for data collection. The scraping process involved a combination of manual and programmatic approaches to interact with the OpenFDA API. OpenFDA provides real-time access to a wealth of information about drugs, devices, and foods, and the Device Recall dataset was the specific focus of this project. API calls were manually conducted to explore the structure of the data and understand the parameters available for querying. This approach allowed for an initial exploration of the OpenFDA API using a web browser. For instance, a sample API call to the Device Recall endpoint:

https://api.fda.gov/device/recall.json?search=product_description:%22Pancreas%22&limit=5

  In this example, the query searches for records in the Device Recall endpoint where the **root_cause_description** exactly matches "Device Design," and it limits the results to the first 5 records. Returned result is displayed as following:

```
{
  "meta": {
    "disclaimer": "Do not rely on openFDA to make decisions regarding medical care. While we make every effort to ensure that data is
    "terms": "https://open.fda.gov/terms/",
    "license": "https://open.fda.gov/license/",
    "last_updated": "2023-12-01",
    "results": {
      "skip": 0,
      "limit": 1,
      "total": 24
    }
  },
  "results": [
    {
      "cfres_id": "149666",
      "product_res_number": "Z-0123-2017",
      "event_date_initiated": "2016-08-02",
      "event_date_posted": "2016-10-18",
      "recall_status": "Terminated",
      "event_date_terminated": "2017-09-07",
      "res_event_number": "75207",
      "product_code": "CDT",
      "k_numbers": [
        "K020238"
      ],
      "product_description": "Randox Lipase (Colorimetric)\n\nProduct Usage:\nA lipase test system is a device intended to measure the
      "code_info": "Catalogue number:    LI3837, LI7979, LI8050, LI8361",
      "recalling_firm": "Randox Laboratories Ltd.\n 55 Diamond Road\n Crumlin (North) Ireland",
      "reason_for_recall": "According to the firm carry over was observed when the Lipase test is run directly before or after the LDL
      "root_cause_description": "Nonconforming Material/Component",
      "action": "Randox Laboratories sent an Urgent Field Safety Notice letter dated June 17, 2016 to affected customers.  The letter
      "product_quantity": "18",
```

To automate the data retrieval process, programmatic API calls were implemented using Python. The **requests** library was employed to send HTTP requests to the OpenFDA API, and the obtained JSON responses were processed for further analysis. Here is a simplified example of a programmatic API call using Python:

```python
import requests


url = "https://api.fda.gov/device/recall.json"

params = {

    'search': 'root_cause_description.exact:"Device Design"',

    'limit': 5

}
```

```
response = requests.get(url, params=params)

data = response.json()
```

The Python **requests** library is used to send a GET request to the specified API endpoint with the defined parameters. The response is then converted to a JSON format, allowing for easy manipulation and extraction of relevant information.

Data Retrieval and Structure

The OpenFDA API returned individual results as JSON objects, comprising two main sections:

meta: Metadata about the query, including a disclaimer, data license link, last-updated date, and total matching records.

results: An array of matching results, dependent on which endpoint was queried.

The structure of the JSON response facilitated efficient extraction and subsequent analysis of the data. The returned data, in JSON format, was cleaned and preprocessed to handle missing values and ensure compatibility for further analysis. In this part, we make our code of retrieve FDA data and format public. Future studies aim to use FDA data could modify the code and put to use. Please see Appendix A for reference.

Data Cleaning

Integral to the successful execution of this project revolved around the meticulous process of data cleansing, a crucial endeavor undertaken to enhance the efficiency and expediency of subsequent data analyses. The strategic emphasis on cleaning the data played a pivotal role in streamlining and optimizing the overall data sets, thus paving the way for a more rapid and insightful exploration of the information at hand. This meticulous data cleansing process not only

contributed to the expeditiousness of subsequent analyses but also laid a robust foundation for the reliability and accuracy of the conclusions drawn from the data-driven insights.

action	addition	address, address	cfres_id	city	device_c	device_n	distribut	event_da	event_da	event_da	fei_numl	k_numbe	k_numbe	medical	postal_c	product_	product_	product_	product_	reason_f	recalling	recall_st	registrat	regulatic	res_ever	root_cau	state
The	800-437-| 9900 Innovation D	202850	Wauwat	2	Compute	Distribu	######	######		['3013250	['K082467	['K213972	Cardiova	53226-48	DQK		Prucka 1	81 ampli	Z-2613-2(	A diode	GE Medi	Open, Cli	['3013250	870.143	92903	Compon	WI
On	Philips		202893		2	Monitor,	US:AZ,	######	######		['3003832	['K04264;	['K201746	Cardiovascular		MHX		Philips		5773	Z-2625-2(	Full scre	Remote (	Open, Cli	['3031156	870.103	92914	Device Design	
Stryker	same	1941 Stryker Way	202688	Portage	2	Cement (	Nation	######	######		['3000215	['K95193(	['K931847	General,	49002-97	LZN		Stryker	16 units	Z-2601-2(	Potentia	Stryker C	Open, Cli	['2648666	878.33	92841	Under In	MI
Ambu	SAME	6721 Col\ Ste 200	202813	Columbi	1	Accessor	Nationw	######	######		['3005099	['K940152',	'K81254	Gastroer	21046-33	FEM		Ambu	2689 unit	Z-2628-2(	Multiple	Ambu In(	Open, Cli	['3005099	876.15	92886	Device D	MD
The firm	747-242-:	22617 Mariano St	196079	Woodlar N		Uv Lamp,	US Natio	######	######					Unknown	91367-61	RHP		The prod	485 units	Z-0003-2(	Excessiv	IN MY BA	Open, Classified			90860	Radiatio	CA
A CryoLife	Connie	1655 Roberts Blvd	26121	Kennesa	3	Heart-Va	One unit	######						Unknown	30144	MIE		CryoValv	1 unit	Z-0676-0	An allog	Cryolife I	Terminated			25595	Other	GA
Consignee was n(	1714 Hayes Street		25925	Nashvill(	3	Heart-Va	GA	######	######	######				Unknown	37203	MIE		One hea	One hea	Z-0677-0	Human t	DCI Donc	Terminated			25493	Other	TN
Field modification	3000 N Grandview		25985	Waukesha		The prod	######	######	######		['K012389']				53186	90LMA		Revoluti	78 device	Z-0157-0	The devi	General	Terminated			25531	Other	WI
Urgent d	800-521-:	6200 Jackson Rd.	29050	Ann Arbor			United S	######	######		['K915193A']				48103	74DWF		Sarns brand	Retro	Z-1191-0	Product i	Terumo (	Terminated			27041	Other	MI
Urgent d	800-521-:	6200 Jackson Rd.	29051	Ann Arbor			United S	######	######		['K925442']				48103	74DWF		Sarns brand	Retro	Z-1192-0	Product i	Terumo (	Terminated			27041	Other	MI
Urgent d	800-521-:	6200 Jackson Rd.	29052	Ann Arbor			United S	######	######		['K925442']				48103	74DWF		Sarns brand	Retro	Z-1193-0	Product i	Terumo (	Terminated			27041	Other	MI
The phys	Sylvie L.	1655 Roberts Blvd	29085	Kennesa	3	Heart-Va	Tissue w	######	######	######				Unknown	30144	MIE		CryoValv	1 unit	Z-0019-0	The hear	Cryolife I	Terminated			27051	Other	GA
The firm	Chris	1641 Edlich Dr	29644	Charlottesville		Product v	######	######	######						22911			Wire Dri	135	Z-0043-0	Wiring p	Microaln	Terminated			27301	Other	VA
Baxter se	Center	120 & Wilson Rd	31080	Round Lake		The prod	######	######	######		['K002679']				60073	FRN--		Baxter 6(	188 units	Z-0376-0	Prematu	Baxter H	Terminated			28037	Other	IL
The cons	Mr. P.	1655 Roberts Blvd	31625	Kennesa	3	Heart-Va	The allo(	######	######	######				Unknown	30144-36	MIE		CryoValv	1 unit	Z-0548-0	As part o	Cryolife	Terminated			28345	Other	GA
The reca	Roland	51 Valley Stream F	40241	Malvern		Nationw	######	######	######						19355-1406			Mammor	33 units	Z-1045-0	potentia	Siemens	Terminated			32515	Other	PA
The firm	Curtis	650 Liberty Ave	44484	Union	f	Pulmoni(	The devi	######	######	######	######	['2025587']				07083-81	MWH		Shelhigh	25 units	Z-0678-0	Unappro	Shelhigh	Terminal	['2025587']		34692	Other	NJ
Bard Ele(	Chris O.	129 Concord Road	25880	Billerica		Nationw	######	######	######						1821			Bard	12 units	Z-0603-0	Sterile b	C. R.Bard	Terminated			25401	Packagin	MA
Consignees notif	604 Queensbury A		25805	Queensbury		There w:	######	######	######		['K000825']				12804			JOGRAPH	50 cathet	Z-0593-0	Fr. cath	Jomed C(	Terminated			25424	Other	NY
The reca	Gene	121 Freeport Rd	25718	Pittsburgh		The devi	######	######	######						1.5E+08			Life Vest	174 units	Z-0578-0	Wires m:	Lifecor Ir	Terminated			25387	Other	PA
A letter (	425-497-:	6675 185(Suite 10(	28199	Redmond	3	Columns	The firm	######	######	######	['301901(	['K831423']		Unknown	98052	LQQ		Prosorba	19 cases	Z-1086-0	No packe	Freseniu	Terminal	['3019016592']		26700	Other	WA
The reca	Roland	51 Valley Stream F	26730	Malvern		The prod	######	######	######		['K9355694']				19355			Magic Vi	49 units	Z-1029-0	software	Siemens	Terminated			25928	Other	PA
Custome	812-934-:	125 E Pearl St	27937	Batesville		United S	######	######	######						47006			Hill-Rom	1,400	Z-1028-0	The cast	Hill-Rom	Terminated			26586	Other	IN
Marketir	877-229-:	1884 Miles Ave.	27494	Elkhart		United S	######	######	######		['K960546']				46515			Clinitek	1324	Z-0911-0	Analyzer	Bayer He	Terminated			26312	Other	IN
Firm con	Melissa	1430 West McCoy	28148	Santa Maria		United S	######	######	######						93455			Blood Ag	11,250 pl	Z-1076-0	Custome	Hardy Mi	Terminated			26681	Other	CA
On 7/17/	425-487-:	22100 Bothell Ever	28537	Bothell		The firm	######	######	######		['K982993']				98041			OmniDia	52	Z-0874-0	Labeling	Philips N	Terminated			26837	Other	WA
The phys	Mr. P.	1655 Roberts Blvd	35342	Kennesa	3	Heart-Va	The tissu	######	######	######				Unknown	30144-36	MIE		CryoValv	1 tissue	Z-0026-0	A pre-im	Cryolife I	Terminated			30191	Other	GA
Smiths S	Timothy	10 Bowman Dr	36257	Keene		FL	######	######	######						03431-5043			Custom	357 case	Z-0463-0	Mislabel	Smiths N	Terminated			30642	Other	NH
Firm sen	Paul	2441 Michelle Dr	37400	Tustin		Nationw	######		######						92781	rad		X-Ray Hi	494	Z-0494-0	Non-com	Toshiba	Terminated			31217	Other	CA
Own nan	800-526-:	9115 Hague Rd	36299	Indianapolis		Nationw	######	######	######		['K932642',	'K97267	46256-1025					Roche br	20116 un	Z-0605-0	A defecti	Roche Di	Terminated			30664	Other	IN
Consigne	Mr. P.	1655 Roberts Blvd	37235	Kennesa	3	Heart-Va	CA, NJ, T\	######	######	######				Unknown	30144-36	MIE		CryoValv	1 tissue	Z-0685-0	During a	Cryolife I	Terminated			31140	Other	GA
The reca	Denis	340 E Ma Ste 204c	37581	Langhorne		The prod	######	######	######						19047-2848			Uterine l	115 units	Z-0727-0	product i	Bioteque	Terminated			31276	Other	PA
1.Fanligt	Linda	14145 Prc Ste 14	46377	City Of Industry		Nationw	######	######	######						91746-28	U28		PlusRite	100,000 t	Z-0454-0	These nc	Fanlight	Terminated			35548	Other	CA
Consigne	734-487-:	5449 Research Dr	46267	Canton		Worldwi	######	######	######		['K992002']				48188-22	CCH		Liquid A(	One unit	Z-1454-0	Unexpec	Pointe Sc	Terminated			35497	Other	MI
Boston S	Robert	1 Boston Scientifi(	25917	Natick		Nationw	######	######	######		['K970052']				1760			Boston	22 units	Z-0551-0	Breach ir	Boston S	Terminated			25487	Other	MA
The firm began to	8200 Carr Ste C-14(		25088	Austin		AL, AZ, Nl	######	######	######						78754-38	---		Ascensi	Unknown	Z-0549-0	Brochure	Ascensic	Terminated			25056	Other	TX
Implanti	Shari L.	1655 Roberts Blvd	27260	Kennesa	3	Heart-Va	The com(	######	######	######				Unknown	30144	MIE		CryoValv	8 units	Z-0866-0	Microorg	Cryolife	Terminated			26205	Other	GA
On 3/25/	Troy	1602 4th Ave	26558	North Billings		The firm	######	######	######						59101			RJ T&A P/	20	Z-0754-0	Product i	Windsto	Terminated			25830	Other	MT
On 3/25/	Troy	1602 4th Ave	26560	North Billings		The firm	######	######	######						59101			BACK PAC	42	Z-0756-0	Product i	Windsto	Terminated			25830	Other	MT
Consigne	Sylvie L.	1655 Roberts Blvd	30303	Kennesa	3	Heart-Va	The tissu	######	######	######				Unknown	30144-36	MIE		CryoValv	One unit	Z-0167-0	CryoLife (	Cryolife I	Terminated			27664	Other	GA

The dataset obtained through web scraping of the FDA website serves as an illustrative example of the extensive efforts invested in collecting pertinent information for our study. The initial dataset, comprising a total of 50,054 devices, exhibited a considerable amount of noise and included numerous data points that were deemed extraneous to the focus of our analysis. To enhance the efficiency and precision of our subsequent analyses, several columns, such as additional contact info, cfres id, device class, fei number, k number, product code, registration number, regulation number, and event number, were identified as irrelevant and subsequently removed from the dataset.

The subsequent challenge in our data preprocessing journey involved narrowing down the dataset to specifically focus on devices related to the pancreas. This categorization was achieved by implementing a keyword-based filter on the "device description" column, targeting terms such as "pancreas," "pancreatic," and "Glucose." Additionally, the inclusion of the keyword "glucose"

was motivated by its association with pancreatic function. As a result of this filtering process, the dataset was refined, reducing the number of devices to a more manageable 79.

With this smaller, more focused sample size, the subsequent task involved coding the "recall reason" column into distinct categories. This categorization was based on the provided reasons for recall, resulting in the classification of devices into groups such as faulty design, incorrect labeling, contamination, or updated requirements. The faulty design category encompassed issues related to the manufacturing process or functionality of the device, such as obstruction of crucial veins or malfunctioning. Incorrect labeling pertained to discrepancies in the information presented on the device's label, including errors in nomenclature or dosage information. Contamination was identified when devices were inadequately sterilized, a critical concern given the potential for these devices to be introduced into the human body. The updated requirements category emerged when changes in regulations, either due to legal mandates or company policies, necessitated the recall of certain devices.

Post-coding and data cleaning procedures, the resultant dataset exhibited a significantly improved level of clarity and relevance, setting the stage for more meaningful and insightful analyses in our ongoing research endeavor.

status	city	state	recalling_firm	method_c	initial_firm	distributio	product_c	recall_rea	recall_start	recall_end	recall_time_days
Ongoing	Marlborou	MA	Boston Scientific Corporation	Voluntary:	Letter	Global	6635	Faulty Des	2/2/2023	4/26/2023	83
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	10	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	6	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	4	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	6	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	4	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	13	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	6	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	6	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	4	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	4	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	14	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	4	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	27	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	10	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	3	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	10	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	1	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	2	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	30	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	8	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Stafford S	CT	Hobbs Medical, Inc.	Voluntary:	Letter	Global	8	Incorrect	7/29/2022	10/19/2022	82
Ongoing	Indianapo	IN	Roche Diagnostics Operations, Inc.	Voluntary:	Letter	National	684	Faulty Des	2/7/2020	3/11/2020	33
Ongoing	Marlborou	MA	Boston Scientific Corporation	Voluntary:	Letter	Global	542	Incorrect	10/21/2019	12/4/2019	44

The meticulous process of cleaning and organizing the dataset in the described manner has proven to be instrumental in facilitating a more streamlined and insightful analysis. By systematically addressing noise and removing irrelevant data points, we have not only enhanced the overall quality of the dataset but also set the stage for more nuanced and meaningful examinations of the information at hand.

This refined dataset has opened up avenues for novel insights, notably including a deeper exploration into the temporal aspects of the recall process. The improved organization of the data has enabled a more granular examination of the timeline associated with the entire recall process. Insights into the duration of various phases, from the initiation of the recall to its completion, now become readily accessible. This newfound capability to analyze the temporal dynamics of the recall process provides a valuable perspective, shedding light on efficiency, response times, and potential areas for improvement in the overall recall management procedures.

Furthermore, the streamlined dataset not only facilitates a more efficient analysis of the existing variables but also allows for the incorporation of additional parameters that may have been

challenging to explore in the presence of noise and irrelevant data. This expanded analytical scope opens the door to uncovering deeper patterns, correlations, and trends that may contribute to a more comprehensive understanding of the factors influencing recalls and their subsequent resolution.

In essence, the effort invested in cleaning and organizing the data has not only optimized the dataset for current analyses but has also empowered the research process with the flexibility to derive fresh insights and explore hitherto uncharted dimensions of the recall phenomena. This exemplifies the iterative nature of data analysis, where the enhancement of data quality serves as a catalyst for continuous refinement and discovery within the research framework.

Exploratory Analysis

Embarking on the next phase of our analytical journey, we turned our attention to the development of visual graphics as a strategic tool to enhance our comprehension of the dataset. The initial focus centered on creating a graphic representation aimed at illustrate patterns related to firms with the highest frequency of recalls.

By leveraging graphical elements, such as bar charts or pie charts, we sought to visually depict the distribution of recalls among different firms. This approach not only facilitates a quick and intuitive assessment of the most recurrent contributors to recalls but also provides a visual narrative that can be instrumental in discerning trends and potential outliers.
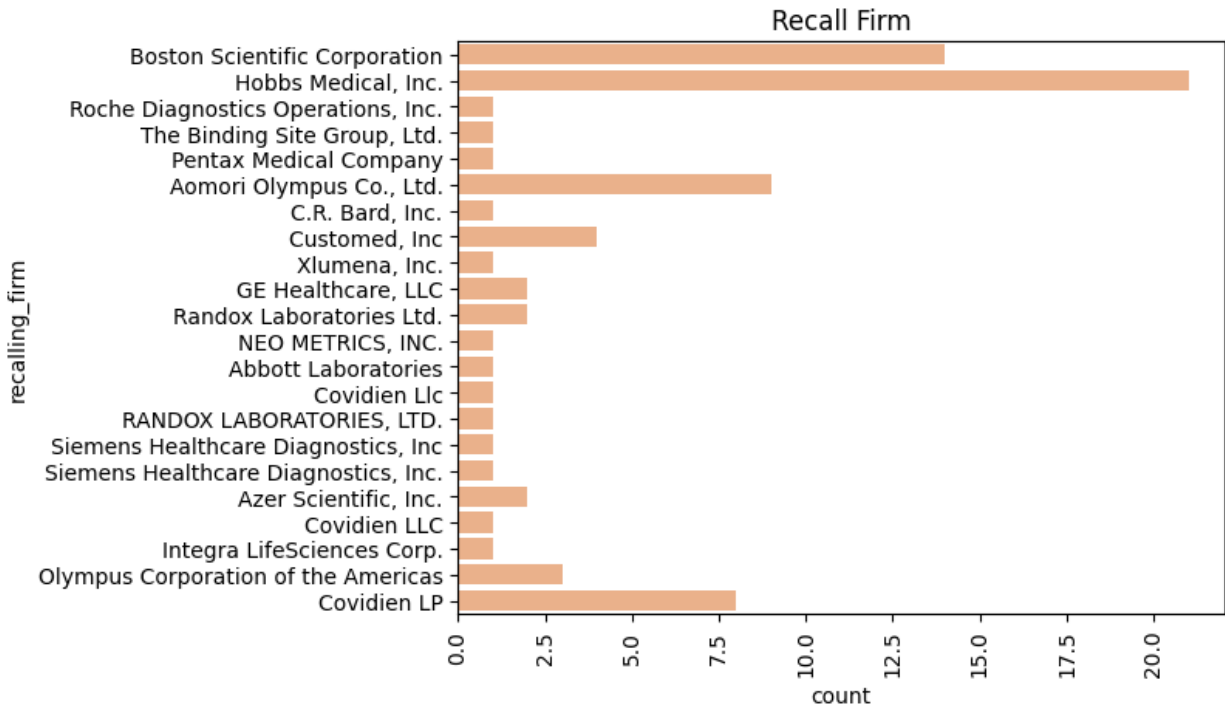
Figure 1

The presented graphic encapsulates a visual representation of various companies and the corresponding number of devices necessitating recall within our sample. Notably, Hobbs Medical, Inc. emerged as the most prominent entity in our dataset, with a substantial recall count of 20 devices. Following closely, the Boston Scientific Corporation exhibited the second-highest recall frequency, involving 13 devices. Aomori Olympus secured the third position with 10 devices requiring recall, and Covidien LP trailed as the fourth, necessitating the recall of 8 devices.

While these figures spotlight the companies with the highest recall rates in our sample, it is imperative to approach these statistics with a nuanced perspective. Drawing conclusions about the quality or adequacy of devices solely based on recall frequency may oversimplify the complexities inherent in the medical device industry. Various factors contribute to the recall

totals of these companies, and it would be premature to assume that a higher recall rate implies inferior product quality.

One plausible explanation for the variation in recall totals among companies lies in their specialization. Companies like Hobbs Medical, Inc. and Boston Scientific Corporation may focus extensively on devices related to the pancreas, potentially resulting in a higher likelihood of recalls in this specific category. Additionally, larger companies, such as Boston Scientific Corporation, often possess more extensive resources and engage in a broader range of product development initiatives. This increased scope of experimentation may lead to a proportionally higher number of recalls compared to smaller counterparts.

In essence, the graphic serves as a starting point for understanding the recall landscape among different companies, prompting further exploration into the underlying factors contributing to these recall frequencies. Acknowledging the multifaceted nature of the medical device industry and the diverse strategies adopted by companies is crucial to deriving comprehensive insights from such visual representations.
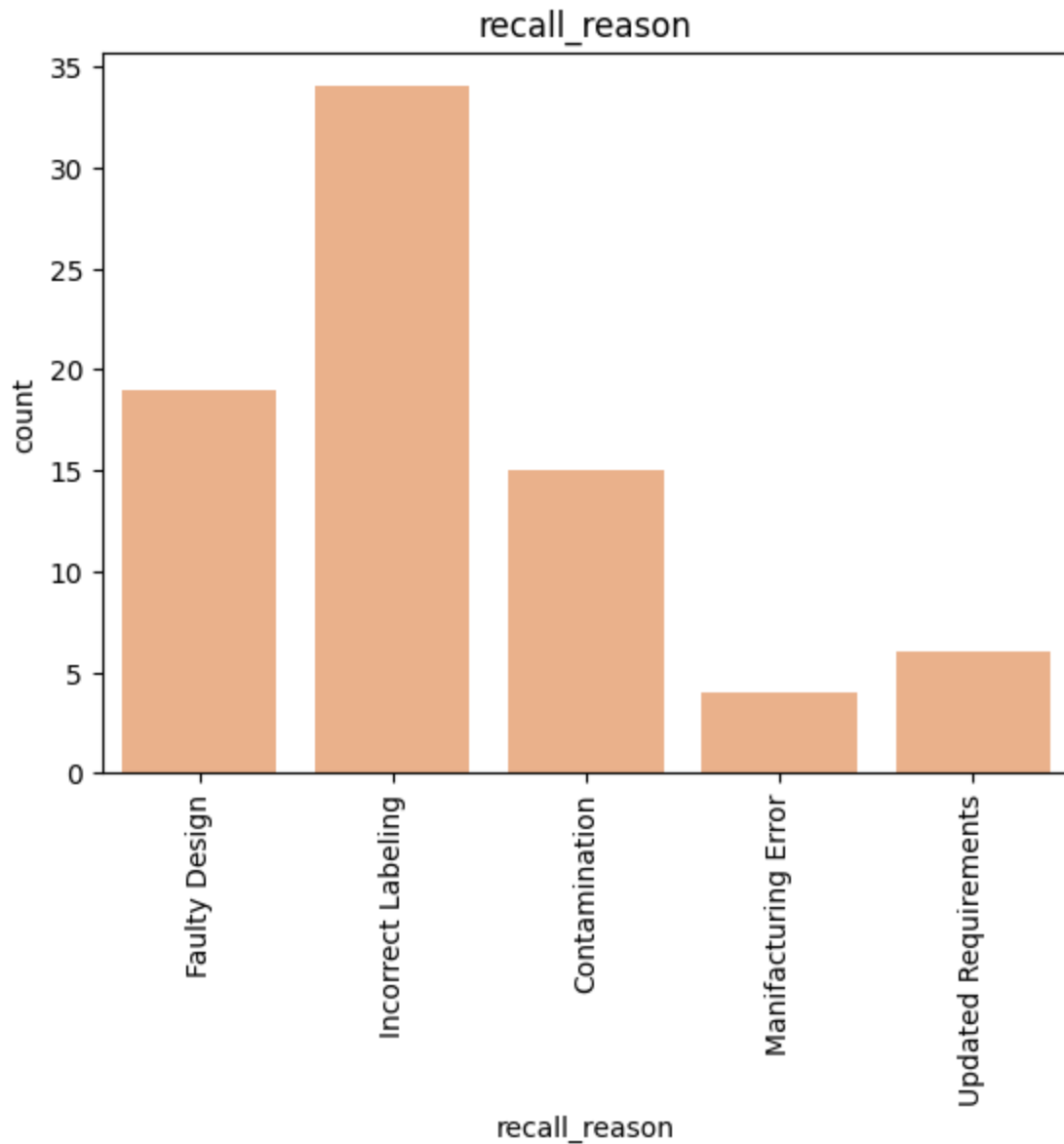
Figure 2

In figure 2, we see a detailed listing of all the categories of problems that prompted the recall in

the first place. Incorrect labelling is by a wide margin the most common reason for issuing a

recall of pancreatic medical devices. Faulty design is a distant second with contamination as a

close third. Manufacturing errors and updated requirements are comparatively uncommon, being

encountered in our datasources much less frequently.

One possible explanation for why labelling errors were so much more common may be due to a lack of rigor in an aspect of the design that may seem less important. Engineers that create such devices may either not pay as much attention to it as they do the functionality itself, or that task may be deferred to a third party who makes the error. Faulty design speaks for itself; the engineers behind it simply made an error in judgement while designing the medical device in question. Contamination is an environmental hazard in which specific devices were deemed unfit to actually be used lest they do more harm than good, not reflective of the efficacy of the device itself.

Observing this data closely reveals a more nuanced understanding of why recalling a device may occur, informing the goals and direction of our study as a whole. Demanding simply for more scrutiny in the design of the devices, while not unwarranted, would not address the most common issue.
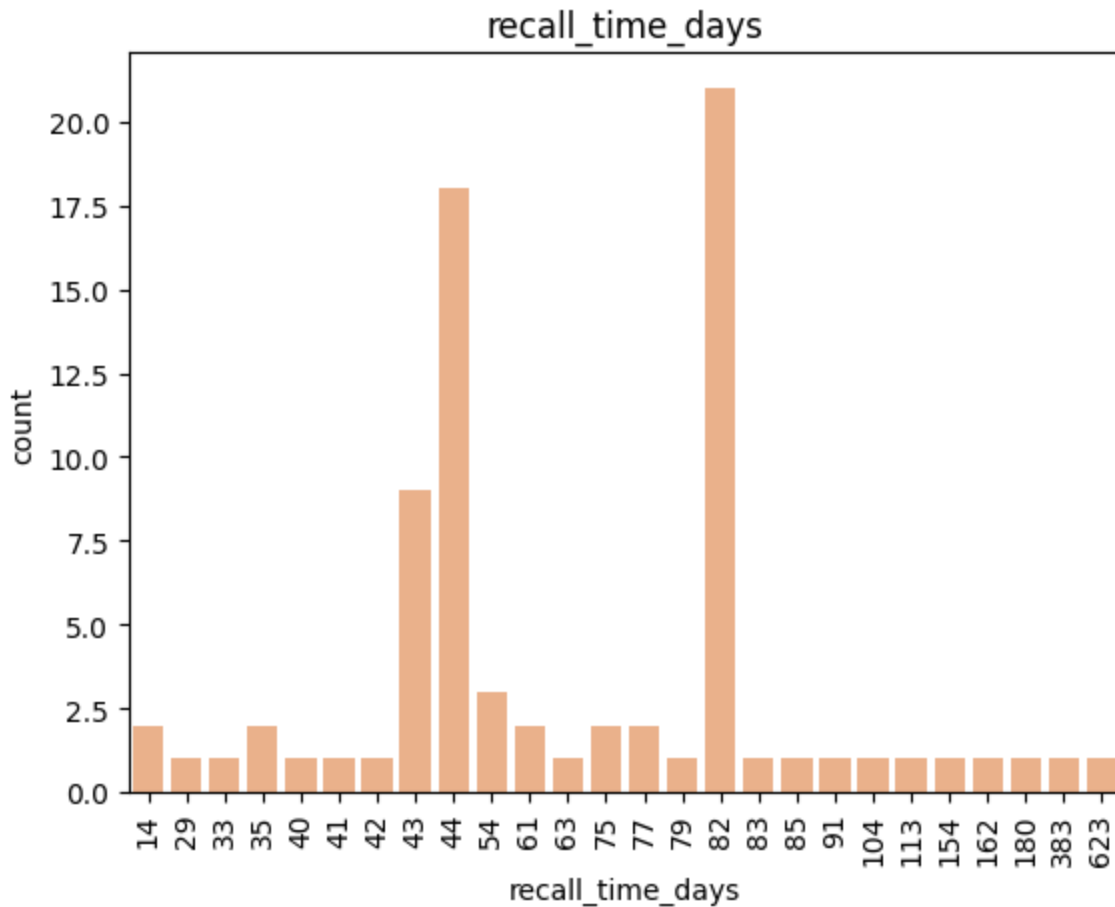
Figure 3

Figure 3 displays the amount of time in days it took for the FDA to procure the recalled

pancreatic medical devices. 82 days is by a wide margin the most frequently occuring number,

with 44 days as a relatively close second and 43 days as a distant third. All the remaining

common numbers are too low to base any substantial judgements upon.

Knowing this, we can estimate that it usually takes approximately three months for the FDA to

fully reclaim any faulty medical devices, if not sooner. While three months is fairly swift given

the scale of the task, that is still plenty of time for someone to receive a faulty or contaminated

device that may harm the recipient. This information is imperative for understanding the

estimated risk that a medical device under recall can pose, and highlights the need for more

thoroughness in the process of evaluating if a device is fit for distribution. It may also point to a
need to enhance the speed at which recalled devices are reclaimed.
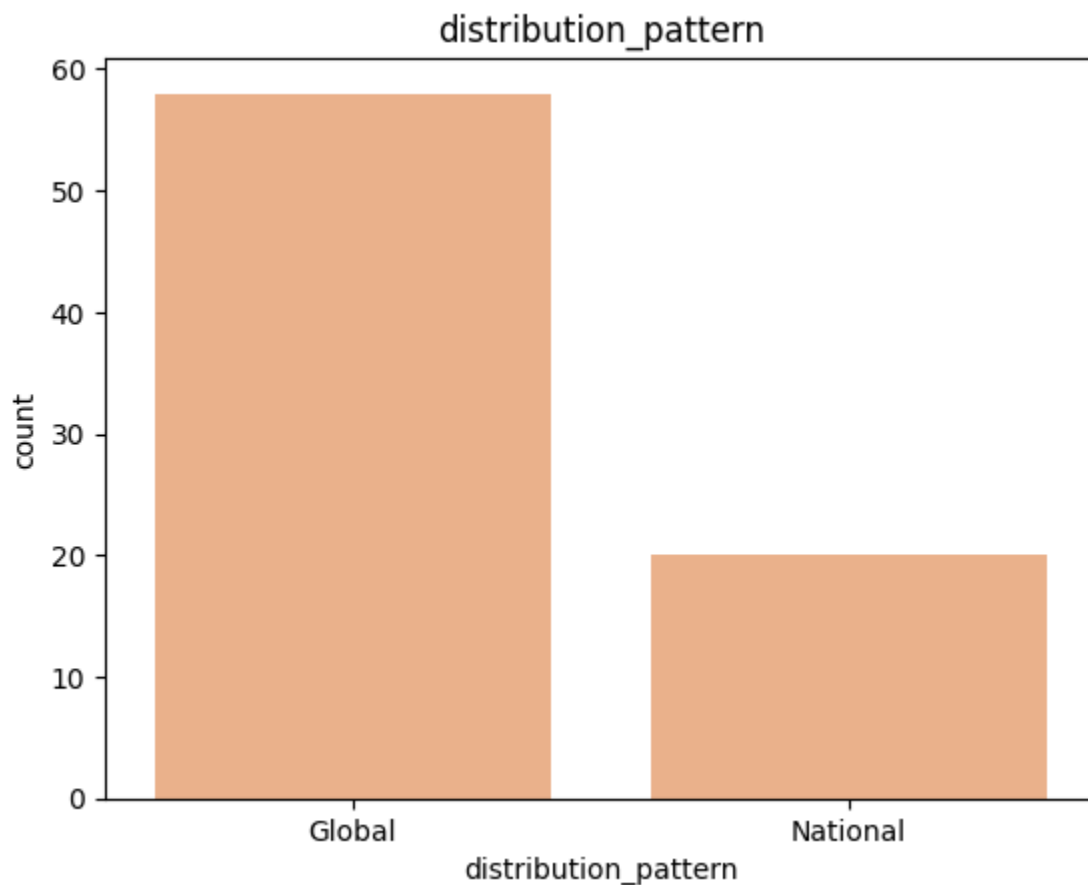
Figure 4

The above graphic is a visualization of how the recalled pancreatic medical devices are
distributed on a much larger scale. As is evident, global distribution make up a larger portion of
of the total distribution patterns. It is worth noting that the "national" variable specifically refers
to the US only, but the "global" variable also includes the US in addition to all other nations
included in our datasources, being the most likely cause for why "global" is so much larger in
comparison. While this alone is not particularly noteworthy, it can provide important context for
future findings and figures.

Product Quanitity

■ Hundreds ■ Thousands ■ Millions

11%

19%

70%
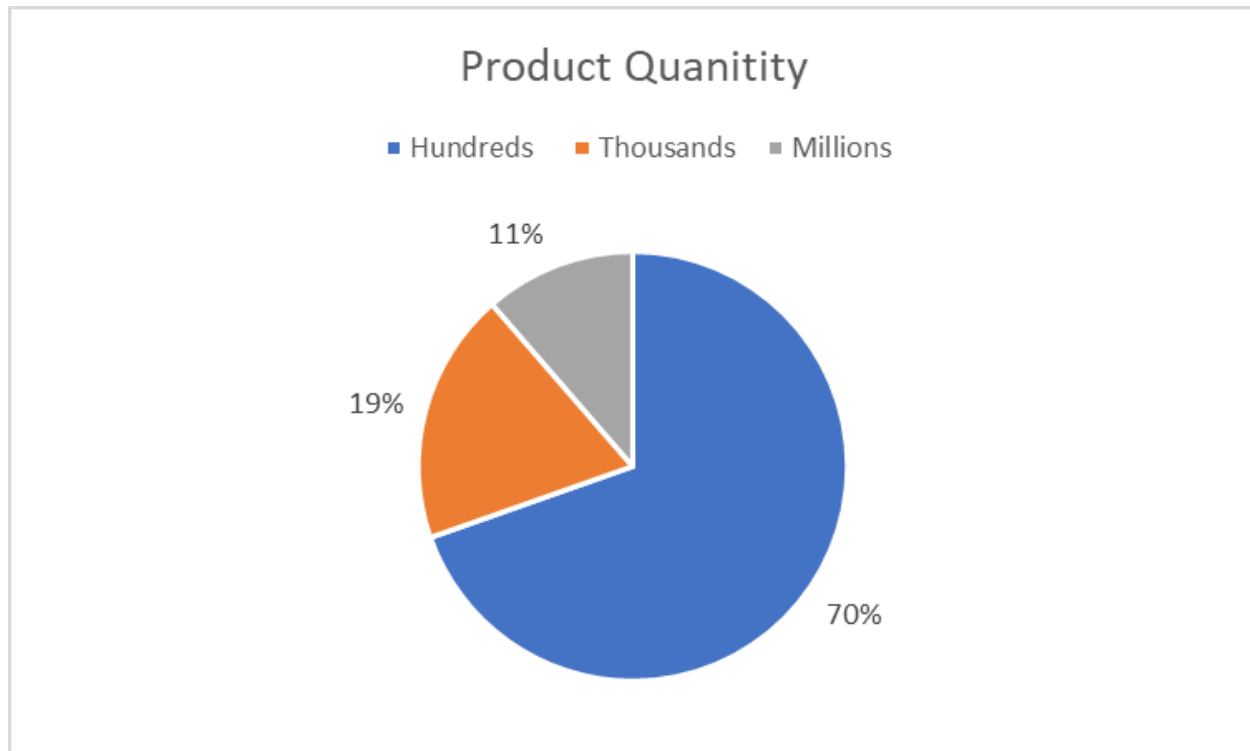
Figure 5

In figure 5 we see the sheer quantity of the prodcusts being recalled. The way the pie chart is structured details the percentage of groups in which the medical devices were recalled. In 70% of cases, the problem was detected relatively soon and only hundreds of devices were distributed before being successfully recalled. Recalls taking place when thousands and millions were distributed were much less common.

The implication of this finding is that the FDA is very quick to detect any anomalies or malfunctions that occur with devices that they approved of. If they were not, then the thousands and millions portions would be far larger, and there would be a significant number of victims due to the erroneous approval. When taking into account the findings of figure 2, this further emphasizes the general level of competence and efficiency possessed by the FDA. Knowing the

quantity of device recalls allows us to gain a stronger grasp on and how that affects overall health for parties that rely on pancreatic medical devices to function normally in day to day life. While the FDA catching the problem quickly 70% of the time is a credit to them, the remaining 30% is large enough to justify more rigorous evaluation methods and training to better ensure safety for a vulnerable population.
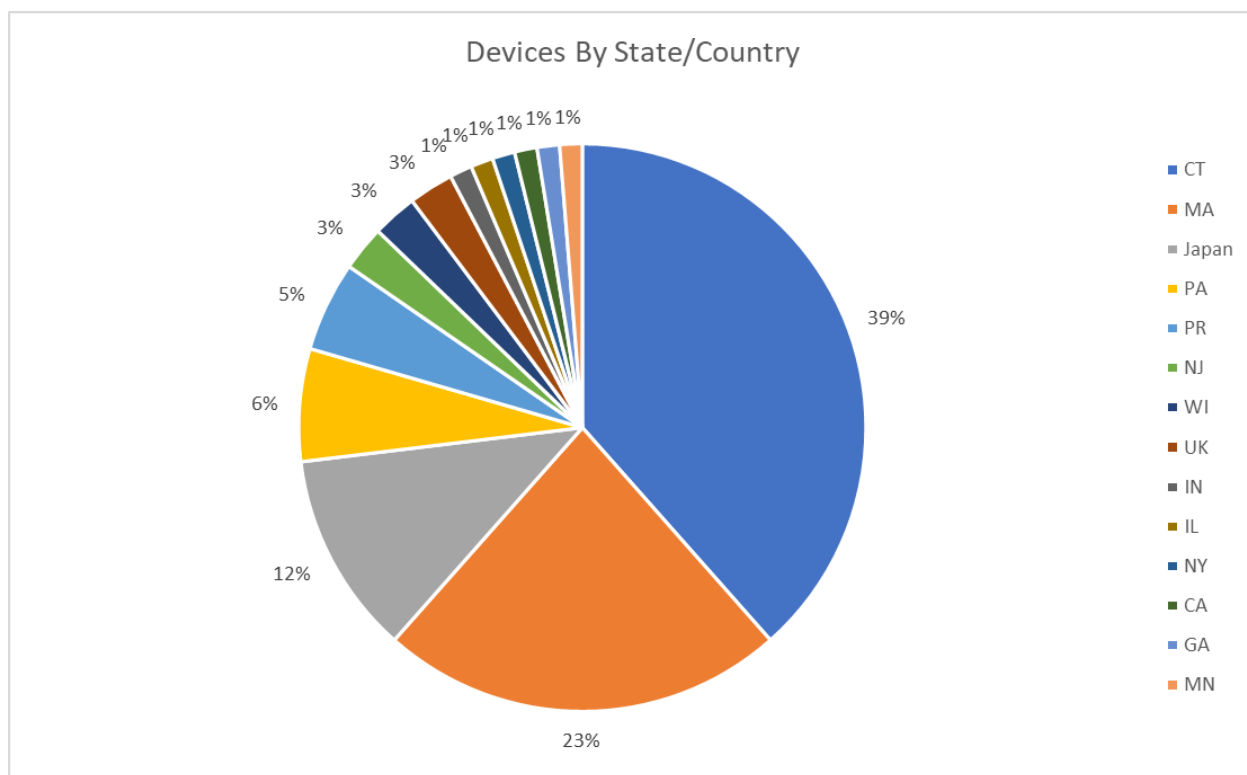
Figure 6

Figure 6 is a breakdown of the states and countries in which devices are distributed. The state of Connecticut is where the most devices are distributed, leading at 39%, followed by the state of Massachussets and then Japan. All remaining states and countries dwindle significantly, making attempts to glean significant information based on them difficult. This could indicate that Conneticut, Massachusetts and Japan have higher levels of patients in need of pancreatic medical devices, meaning they may feel the affect of faulty devices more acutely than other areas.

Reference

American Diabetes Association. (2021). This reference discusses the role of the pancreas in regulating blood glucose levels through the secretion of hormones like insulin and glucagon, which are central to diabetes management.

Ball, et al. (2018). This reference emphasizes the importance of understanding the factors leading to the recall of pancreas medical devices to improve device reliability and efficacy.

Desai, S., & Gross, C. P. (2018); Heinemann, L., & Krinelke, L. G. (2012). These references focus on the research and advancements in the design and functionality of pancreas-related medical devices, including improvements in sensor technology and insulin delivery systems.

Forsmark, C. E. (2017). This reference provides information on the exocrine function of the pancreas, particularly in the production of digestive enzymes necessary for the breakdown and absorption of nutrients.

Hauser, R. G., et al. (2010). This source discusses the complexity and impact of the medical device recall process on patients, particularly those using devices for chronic conditions.

Kesselheim, et al. (2011). This study found that most device recalls were due to problems that could have been identified with more rigorous pre-market testing, highlighting the need for a comprehensive approach to device evaluation.

Klonoff, D. C. (2018). This reference highlights the critical importance of the reliability and efficacy of medical devices like insulin pumps and continuous glucose monitoring systems in managing diabetes and the serious health risks associated with their malfunction.

Liebel, et al. (2018). This reference underscores the critical nature of addressing medical errors, including those related to device failures or design flaws, within the healthcare system.

Maitra, A., & Goggins, M. (2020). This source discusses the health implications of pancreatic disorders such as diabetes, pancreatitis, and pancreatic cancer, and the necessity for effective medical interventions.

McAdams, et al. (2018). This study on insulin pump failures highlights the potentially life-threatening consequences of mechanical and software malfunctions in these devices.

Shuren, J., & Califf, R. M. (2016). This reference discusses the FDA's pivotal role in ensuring the safety and efficacy of medical devices, including their post-market surveillance systems.

Vallis, M. (2016); Polonsky, W. H., & Hessler, D. (2015). These sources discuss the importance of comprehensive patient education and training in ensuring correct usage of medical devices, thereby improving patient outcomes.

Zhou, et al. (2022); Smith, et al. (2019). These studies address recalls in medical devices intended for pancreatic function assistance due to various reasons like software errors, hardware malfunctions, and inaccurate readings.

Zuckerman, et al. (2011). This source emphasizes the necessity for stringent regulatory oversight and rigorous testing protocols for medical devices, particularly those related to the pancreas.

Appendix A

```
import requests

import json

import os


# URL of the JSON file containing links to the data files

json_url = "https://api.fda.gov/download.json"  # Replace with the actual JSON URL


# Directory where you want to save the downloaded data files

download_directory = "./openFDA_data"


# Send a GET request to fetch the JSON file

response = requests.get(json_url)

json_data = json.loads(response.text)


keys = json_data['results'].keys()

keys


# Importing libraries

import json

import csv


# Loading JSON data

with open('./device-recall-0001-of-0001.json', 'r') as file:

    data = json.load(file)
```

```python
# Exploring JSON data
len(data['results'])


# Exploring JSON keys
json_data = data['results'][5]
json_data.keys()
for key in json_data.keys():
    print(key)


# Extracting sub-JSON data
sub_json_data = json_data['openfda']
sub_json_data.keys()


# Creating CSV files for specific keys
for tag in ["k_numbers", "address_2", "event_date_terminated"]:
    print(tag)
    csv_file = './recall/' + tag + '.csv'


    # Open the CSV file for writing
    with open(csv_file, 'w', newline='', encoding='utf-8') as csvfile:
        # Create a CSV writer
        csv_writer = csv.writer(csvfile)


        # Write the keys (field names) as the first row
        csv_writer.writerow(["ID", tag])


    # Writing data to CSV files
```

```python
for num in range(0, 50053):
    json_data = data['results'][num]
    with open(csv_file, 'a', newline='', encoding='utf-8') as csvfile:
        # Create a CSV writer
        csv_writer = csv.writer(csvfile)


        row_without_last_column = {key: value for key, value in json_data.items() if key == tag}
        # Write the corresponding values as the second row
        try:
            value = list(row_without_last_column.values())[0]
            csv_writer.writerow([num, value])
        except:
            csv_writer.writerow([num, ])


# Creating CSV files for keys in the main JSON data
for tag in json_data.keys():
    print(tag)
    csv_file = './recall/' + tag + '.csv'


    # Open the CSV file for writing
    with open(csv_file, 'w', newline='', encoding='utf-8') as csvfile:
        # Create a CSV writer
        csv_writer = csv.writer(csvfile)


        # Write the keys (field names) as the first row
        csv_writer.writerow(["ID", tag])
```

```python
# Writing data to CSV files
for num in range(0, 50053):
    json_data = data['results'][num]
    with open(csv_file, 'a', newline='', encoding='utf-8') as csvfile:
        # Create a CSV writer
        csv_writer = csv.writer(csvfile)


        row_without_last_column = {key: value for key, value in json_data.items() if key == tag}
        try:
            value = list(row_without_last_column.values())[0]
            csv_writer.writerow([num, value])
        except:
            csv_writer.writerow([num, ])


# Creating CSV files for keys in the sub-JSON data
for tag in ["fei_number", "registration_number", "k_number"]:
    print(tag)
    csv_file = './recall/' + tag + '.csv'


    # Open the CSV file for writing
    with open(csv_file, 'w', newline='', encoding='utf-8') as csvfile:
        # Create a CSV writer
        csv_writer = csv.writer(csvfile)


        # Write the keys (field names) as the first row
        csv_writer.writerow(["ID", tag])
```

```python
    # Writing data to CSV files

    for num in range(0, 50053):

        sub_json_data = data['results'][num]['openfda']

        with open(csv_file, 'a', newline='', encoding='utf-8') as csvfile:

            # Create a CSV writer

            csv_writer = csv.writer(csvfile)


            row_without_last_column = {key: value for key, value in sub_json_data.items() if key ==
tag}

            # Write the corresponding values as the second row

            try:

                value = list(row_without_last_column.values())[0]

                csv_writer.writerow([num, value])

            except:

                csv_writer.writerow([num, ])


# Merging CSV files into a single DataFrame

import pandas as pd

import os


# Specify the folder where your CSV files are located

folder_path = './recall'  # Replace 'path_to_folder' with the actual folder path


# Get a list of all CSV files in the folder

csv_files = [f for f in os.listdir(folder_path) if f.endswith('.csv')]


# Initialize an empty dictionary to store data from each CSV file

data = {}
```

```python
# Read each CSV file and store its content in the dictionary
for csv_file in csv_files:
    column_name = os.path.splitext(csv_file)[0]  # Use the file name as the column name
    file_path = os.path.join(folder_path, csv_file)
    data[column_name] = pd.read_csv(file_path)


# Merge the data from the dictionary into a single DataFrame
merged_data = pd.concat(data.values(), axis=1)


# Specify the path and filename for the merged CSV file
merged_csv_filename = 'merged_data.csv'


# Save the merged DataFrame to a CSV file
merged_data.to_csv(merged_csv_filename, index=False)


print(f'Merged data saved to {merged_csv_filename}')
```