ConText: Supporting the Pursuit and Management of Evidence in Text-based Reporting Systems

Tabassum Kakar[1], Xiao Qin[1], Elke Rundensteiner[1], Lane Harrison[1], Sanjay Sahoo[2], Suranjan De[2] and Thang La[2]

[1] *Worcester Polytechnic Institute, Worcester, MA, U.S.A.*

[2] *U.S. Food and Drug Administration, Silver Spring, MD, U.S.A.*

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Abstract: Instance-based Incident Analysis (IIA) – a labor intensive and error-prone task – requires analysts to review text-based reports of incidents, where each may be evidence of a larger problem that requires regulatory action. Given the rise of reporting systems in many organizations, there is a need to explore tools that may aid IIA analysts in exploring, evaluating, and generalizing findings across a large set of independently produced reports in a unified workflow – currently not supported by existing tools. In this work, we contribute a design study conducted in collaboration with Pharmacovigilance experts at the US Food and Drug Administration. Following a series of interviews and discussions focused on workflows and toolsets, we develop a prototype, ConText, which combines domain-informed computational methods with interactive visual displays to support evidence identification, collection, and management for IIA. We evaluate ConText via case studies and follow-up semi-structured interviews, depicting its effectiveness in performing IIA tasks of evidence collection and monitoring. We discuss insights derived from the design and evaluation of ConText that may be valuable for designing future interactive analytic systems for life-critical IIA workflows.

1 INTRODUCTION

Text-based reporting systems are prevalent across a wide sector of regulatory organizations. In Pharmacovigilance, the U.S. Food and Drug Administration (FDA) monitors adverse event reports submitted by patients to identify adverse drug reactions or medication errors (Härmark and Van Grootheest, 2008). In the aviation industry, the US Federal Aviation Administration (FAA) is mandated to investigate service difficulty reports to better identify ongoing maintenance issues with aircraft (SDR, 2021; Marais and Robichaud, 2012). Similarly, the US Consumer Financial Protection Bureau (CFPB, 2021) is responsible for collecting and analyzing consumer complaints about unfair, or deceptive financial practices.

We refer to these reports as *incident reports*, and the activities analysts perform in these critical text-based reporting systems as *Instance-based Incident Analysis* (IIA). A common goal for IIA is to analyze and then organize incoming reports such that the relevant incident reports serving as evidence for a particular issue are captured within one coherent collection (Kakar et al., 2019b). This report collection can then be used as evidence for regulatory decision-making on products or services. IIA activities require analysts' judgement throughout the process to make decisions on the importance and relevance of each report to an investigation, hence making IIA a suitable candidate for interactive analytics approaches.

In this work, we focus on Pharmacovigilance as a *case domain for IIA*, where robust detection of adverse reactions and medication errors represents a life-critical task, as adverse reactions are one of the leading causes of death worldwide (Lazarou et al., 1998). Given this criticality, drug safety analysts must perform due diligence on hundreds of incident reports on a daily basis, with the aim of identifying reports as evidence to a suspected drug safety problem.

When these analysts find an incident of concern with a particular drug or medical treatment, they tend to pivot their analyses toward finding and organizing similar incidents to *build a case for action* (Kakar et al., 2019b). These cases need continuous management as instances of evidence are received over time. Cases may take longer to

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conclude as enough evidence is needed to confirm a potential problem. Thus, analysts continuously monitor multiple cases and add evidence to them as reports are received weekly.

In this paper, we present a design study involving a prototype tool, ConText, designed in collaboration with FDA analysts that aims to support them in Instance-based Incident Analysis (IIA). ConText assists an analyst to interactively examine individual text narratives aided by domain-informed NLP-generated interest points *to identify evidential information within a report.* ConText then realizes a systematic approach for assisting analysts in finding instances of evidence to *build and strengthen a case* supporting the occurrence of a critical incident, and *interactively managing multiple ongoing cases* by leveraging analysts' knowledge and findings. We evaluate the effectiveness of ConText for IIA via case studies and interviews.

Contributions of this work include:

- Characterization of the Instance-based Incident Analysis (IIA) workflow and ongoing challenges through in-depth analysis of IIA practices via a series of interviews and follow-up discussions with domain experts at the FDA.
- ConText, an iteratively designed IIA-focused prototype that includes a composition of visualization and domain-informed computational elements designed to aid analysts in evidence collection and management by providing a unified workflow.
- Recommendations following insights gained during the development and evaluation of ConText that opens opportunities in human-computer interaction and visualization for designing future systems supporting IIA.

2 BACKGROUND AND RELATED WORK

2.1 Incident Report Analysis

Much of the existing work in Pharmacovigilance has focused on applying computational techniques on incident reports to detect potential drugs causing reactions (Karimi et al., 2015). Extensive work developing natural language processing (NLP) techniques to extract key information from clinical notes and incident reports (Wunnava et al., 2020) also exists. These techniques alone, however, are not sufficient due to the analysts' judgement being core to IIA, making it a viable candidate for interactive analytics.

On the other hand, publicly available online tools such as OpenFDAVigil (Böhm et al., 2016) allow the general public explore incident reports and get basic statistics about the reports. Other approaches have visualized relationships between drugs and their reported reactions (Jian-Xiang et al., 2015; Kakar et al., 2019b). These works do neither characterize nor support the broader scope of IIA activities performed by the analysts. Apart from this, we are not aware of studies to understand IIA tasks or approaches that use interactive analytics to support such tasks performed in other domains, such as, aviation (SDR, 2021) and financial services (CFPB, 2021).

2.2 Visual Document Analytics

The majority of the existing visualization techniques for text analysis center around designing summaries of a set of documents using topic analysis, word-clouds or meta information from text (Liu et al., 2018; Görg et al., 2013; Kakar et al., 2019a).

These overviews may be potentially applied to screen a particular problem represented by a set of reports. Our goal instead is to support evidence identification and collection for a potential problem, screened using one of these overview techniques (Kakar et al., 2019a; Görg et al., 2013).

Extensive research work has been done to design visual tools for 'close reading' of literary texts, such as books and poems (Jänicke et al., 2015). These tools help in understanding the structure and content of the literary documents. Literary texts are different than incident reports in the sense that the later corresponds to *problem-centric* documents to be investigated with the sole purpose to assess the reported incidents.

In the medical domain, visual analytics tools target the analysis and summarization of electronic health records (EHR) and clinical notes (Shneiderman et al., 2013; Sultanum et al., 2018). The majority of these tools display overviews of patient's medical history consisting of multiple events to help the medical professionals with diagnosis or treatment. Conversely, in IIA, analysts identify an issue that is happening to multiple patients and build a case by collecting evidence about similar incidents to take a regulatory action.

2.3 Analytics Record Keeping Tools

Extensive research has been conducted to manage and annotate insights during exploration (Chen et al., 2010; Gotz et al., 2006) which resembles our *case management task*. Harvest (Shrinivasan et al., 2009) provides a mixed-initiative based approach to automatically recommend notes and concepts from past analyses that are relevant to the current analysis. Sandbox (Wright et al., 2006) is a gesture-based editor for collecting and managing insights and discoveries on a visualization. Click2annotate (Chen et al., 2010) provides automatically computed editable templates for interpreting outliers and clusters. Jigsaw's successor (Liu et al., 2010) supports insight capturing using text-diagramming, that allows an investigator to sketch their findings on a timeline.

These systems target the design of interactive techniques to allow analysts frame relevant information together and clarify connections between data points. Our goal instead is to use analysts' captured insights to support evidence collection for ongoing investigations to assist the IIA workflow.

2.4 Investigative Tools

Investigative tools such as Jigsaw (Stasko et al., 2008; Görg et al., 2013) focus on finding relationships among data entities within and across documents, constructing visualizations around these relationships. While like Jigsaw, we extract key information from the text narratives, one difference is that exploration in JigSaw ends with reading the individual documents (Stasko et al., 2008), while ConText's workflow starts with the analysis of individual report and mainly focuses on collecting independent instances of evidences for similar problem. Moreover, ConText supports interactive tracking of multiple simultaneous cases required for IIA. For IIA, Jigsaw can be used to screen a certain problem, while ConText supports the tasks of evidence identification, collection, and management for the screened problem.

On the other hand, bug tracking tools aim to resolve bugs related to software or issues related to products or services (Serrano and Ciordia, 2005; Avnon and Boggan, 2010). The majority of such tools (Serrano and Ciordia, 2005) aim to resolve software bugs by assigning the problem tickets to respective agents and track the status of their resolution. In contrast, our goal is to support the intermediate steps, i.e., the evidence identification and collection to be able to initiate an action to be taken towards the resolution of a problem. Similarly, in cybersecurity, tools have been designed to help operators quickly identify and address network intrusions and incidents (Amershi et al., 2011). Like cybersecurity, our goal of finding critical issues remains, but the data, challenges, and workflows of security and drug incident response domains vary— requiring thorough design, development, and evaluation of incident management and response tools for Pharmacovigilance.

3 UNDERSTANDING THE IIA WORKFLOW AT THE FDA

This work is part of our over two and a half years collaboration with the FDA to design visual analytics to improve their drug safety review process.

3.1 Methodology

For this project, we conducted a series of semi-structured in-person interviews and follow-up discussions with five (5) domain experts who were drug safety analysts, to understand their IIA workflow, tools, and challenges. In our preliminary interviews, we observed the drug safety analysts performing their routine review tasks in a think-aloud manner. We recorded these interviews and transcribed them to get concrete design requirements for ConText.

After these preliminary interviews we had biweekly remote meetings and email discussions with three of these experts to get more feedback initially on the requirements and validation of our understanding of the review process, and eventually on the design of ConText during the later stages of the project. Overall the project took about eight months from requirement analysis to development detailed in Section 6.

3.2 Background on Incident Reports

Based on our interviews we learned that the U.S. Food and Drug Administration (FDA) regularly receives medical incident reports about medication errors and adverse reactions through their adverse event reporting system know as FAERS (FDA, 2021). These reports are submitted by consumers, health-care professionals and drug manufacturers. Each report has structured information such as demographics of the patients and therapy related information and an unstructured narrative describing the details of the adverse event suspected to be caused by the drug.

3.3 Current IIA Practices at the FDA

Based on our extensive analysis and discussions with the domain experts, we express our understanding of

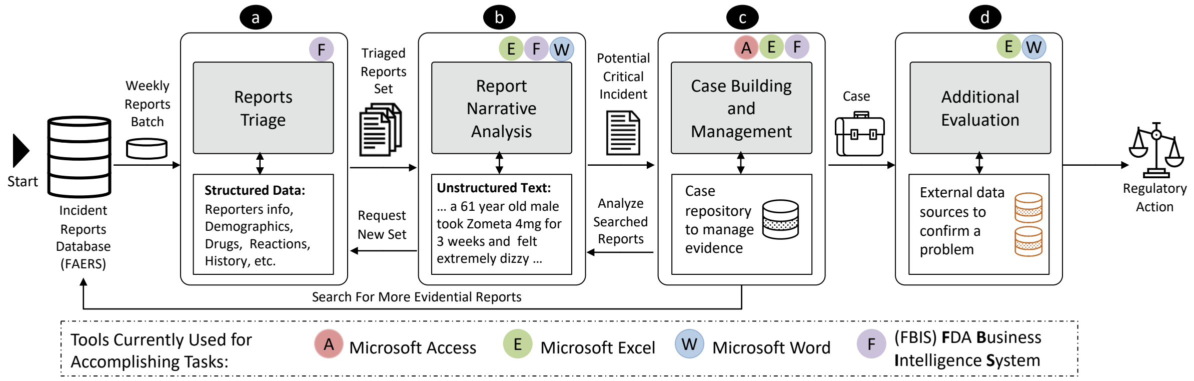

Start
Incident Reports Database (FAERS)
Weekly Reports Batch
a
F
Reports Triage
Structured Data: Reporters info, Demographics, Drugs, Reactions, History, etc.
Triaged Reports Set
Request New Set
b
E F W
Report Narrative Analysis
Unstructured Text: ... a 61 year old male took Zometa 4mg for 3 weeks and felt extremely dizzy ...
Potential Critical Incident
Analyze Searched Reports
c
A E F
Case Building and Management
Case repository to manage evidence
Case
d
E W
Additional Evaluation
External data sources to confirm a problem
Regulatory Action
Search For More Evidential Reports
Tools Currently Used for Accomplishing Tasks:
A Microsoft Access
E Microsoft Excel
W Microsoft Word
F (FBIS) FDA Business Intelligence System

Figure 1: Instance-based Incident Analysis (IIA) workflow in the FDA with tools supporting each task. Tasks (a & d) are out of the scope of this work.

the current IIA workflow at the FDA as depicted in Fig. 1. Incident reports about suspected drug-safety problems are investigated every week in a batch-wise manner to find potential reactions and errors caused by medical products. The goal of the analysts is to find if any of these reports is discussing a real potential problem and indeed is worthy of further investigation and ultimately warranting regulatory action.

Teams of drug safety analysts review these reports based on the medical products assigned to them to detect potential critical incidents. The analysts triage reports related to a suspected drug-safety problem based on structured information associated with each report in the FAERS, such as severity of the incidents (Fig. 1a). If the analysts find a report indicative of a problem, they examine the text narratives of the triaged report to analyze the details of the incident and identify if the narrative has enough information and can serve as evidence to the reported problem (Fig. 1b).

Once an incident is identified as evidence to a suspected problem, other reports that could potentially further corroborate the incident, are collected to build a case to be presented to the management for further evaluation (Fig. 1c). Once sufficient evidence is compiled that can confirm the problem then regulatory actions are taken (Fig. 1d). These actions include adding warnings to the drug label or in worst case removing the product from the market (Härmark and Van Grootheest, 2008). In this paper, we only focus on narrative analysis to identify evidential reports and case building and management to collect and monitor evidence (Fig. 1b & c).

Next we describe a real example of IIA revealing its importance and the challenges involved.

3.4 Motivating Real World IIA Scenario from FDA

In 2012, the FDA analysts were conducting their routine review of reports to find drug safety problems. During the analysis of one of the report's narrative (Fig. 1b), the analyst observed that a patient using steroid injection was hospitalized due to a rare adverse reaction "fungal meningitis". This was an unexpected and critical adverse event. The analyst thus decided to open an investigation about this incident and searched through the database to see if other similar incidents had been reported (Fig. 1c).

After exhaustively searching and collecting other evidential reports, they built a case and found that these patients received steroid injections from the New England Compounding Center (Fig. 1d). The investigation was concluded with an order of inspection of the facility. Later, it was revealed that the product was contaminated due to the violation of safety standards. Thus regulatory actions were taken (FDA, 2018). This incident corresponds to the well-known fungal meningitis outbreak scandal in Massachusetts that killed 64 people and hospitalized 700 nationwide (FDA, 2018).

Clearly, the more effectively we can support the tasks of such investigative process (Fig. 1b & c), the faster we can solve potentially life threatening health issues, such as the crisis described above.

3.5 Challenges in Current IIA Practices

Analysts currently perform IIA tasks manually using a variety of tools to analyze the narratives (Fig. 1b) and collect further evidence to build a case (Fig. 1c) if the report is indicative of investigation. For instance, analysts use FAERS Business Intelligence System (FBIS) (BIFACT, 2019) to compose SQL-based search queries to retrieve relevant reports from the FAERS database using the structured information. Analysts use Microsoft (MS) Excel and MS Access to keep track of their ongoing investigations by manually recording reports evidence to these investigations. Similarly, MS Word is used to search through the narratives text when investigating a particular incident.

These current practices utilise tools and techniques that require a manual trawl through the reports, which is time-consuming, laborious and error prone. Moreover, in IIA, evidence is collected over time as reports are reviewed every week, manually keeping track of the open investigations and adding evidence as they are received, solely relies on the analysts' memory. This becomes even challenging for the investigations that are open for a longer period of time, i.e., months even years. While, analysts are the drivers of the IIA process – their judgment and perspective is crucial to make decision on a report's importance and opening an investigation – a unified tool is needed that leverages computational and interactive features to help them efficiently achieve their goals of evidence identification, collection, and management.

4 IIA TASKS AND DESIGN REQUIREMENTS

Below we describe the core tasks derived from our interactions (Section. 3) with the domain experts.

T1 Identify Evidential Information within a Report. Analysts review every report to make sure not to miss any potential problem that is critical to the organization. The goal is to identify if any of the reports can serve as evidence to the problem. Analysts seek specific information within a report to assess if the report has evidential information. This key information includes the demographics of the patient, the drugs taken by the patient and the observed reactions. Other factors such as medical history and symptoms etc. are also assessed.

T2 Collect Evidence and Build Case-series. Once a suspected problem is escalated, substantial evidence (reports) is needed to support that a drug might be causing the reaction. When the first report serving evidence to a problem, is discovered, reports are searched over a longer period of time to see if further evidence exists. Analysts formulate queries and refine them continuously to get all the relevant reports that represent additional evidence.

T3 Track Multiple Case-series. Due to a high number of potential suspected problems (thousands of drugs and reactions), a large number of case-series may be opened simultaneously for ongoing investigations of multiple problems, as investigations for drug-safety problems generally take longer to be concluded. In addition, due to *recurrence*, new case-series are formed as new reports are received and analyzed every week. Thus, keeping track of all active case-series and collecting relevant evidence for them while keeping an eye on the new batch of reports to not miss an alarming problem is extremely challenging.

As opposed to doing these tasks manually and with no guidance, ConText combines them into a single workflow and provides interactive views and features to augment the analysis. To formally justify the design components and features discussed throughout the rest of this paper, we define a set of guidelines that ConText should adhere to:

DG1 Highlight Evidential Information within Report. The key information within a text narrative that can be used as evidence to confirm the suspected problem should be easily identifiable.

DG2 Support Instance-based Evidence Search. Analysts extensively formulate and refine queries based on keywords from an identified evidential report to find other similar reports that can serve as evidence to the suspected problem. The system should compose such queries automatically and allow analysts to interactively curate them.

DG3 Facilitate Automatic Tracking of Multiple Cases. The system should keep track of the open cases (investigations) by automatically identifying instances of reports evidence to these cases as they are received every week and notify the analysts to validate such findings.

ConText contains three visual components to fulfill these requirements. For **DG1**, the Incident Analysis View is designed to help analysts identify evidential information within a report. In consideration of **DG2** and **DG3**, the Case Management Dashboard is designed to help in evidence collection to build and monitor cases, respectively.

5 DESIGNING ConText FOR IIA

ConText is designed to achieve the IIA tasks to identify, collect, and monitor evidence for ongoing investigations in a unified manner. ConText has two main components, the *Incident Analysis View* (Fig. 2) and the *Case Management Dashboard View* (Fig. 4).

5.1 Incident Analysis View

The incident analysis view provides the line-listing of the reports (Fig. 2-Left) along with the Content analysis panel (Fig. 2-Right) for narrative analysis. An analyst can select a report from the line-listing and analyze its text narrative to interactively identify evidential information using the features below.

Domain-informed Access Points. Analysts need to identify the evidential information in the text narratives that can help them assess if the report indeed necessitates the opening of an investigation. ConText aids analysts to locate the important relevant information (access points) within the text quickly via natural language processing (NLP). These domain-informed access points include the data elements requested by the analysts to be extracted such as drugs, reactions and demographics. Though various techniques to extract name entities from biomedical text exist (Allahyari et al., 2017; Wunnava et al., 2017), we leverage the MEFA framework, that uses a combination of rule-based and machine-learning-based name-entity recognition techniques to extract the key information from the FAERS reports narratives (Wunnava et al., 2017).

Fig. 2 depicts a text narrative with highlighted access points extracted using NLP to guide the analyst. We provide an option to interactively correct or update any inaccurate extracted information using the annotation menu (Fig. 2f). Further, these access points can be toggled on or off based on the analyst's preference. Options to search within the narrative are also provided (Fig. 2e).

User Driven Annotations. Besides the access points, ConText also provides the analyst with the ability to add free-form comments linked with an evidential report or mark interesting keywords or phrases while reading and analyzing a document. Such direct annotations from the analyst are very useful. First, analysts can remember their insights and findings when the document is reviewed again at a later time. Second, these annotations can be helpful in capturing the information that is important to the analysts for assessing an incident, and thus can be leveraged to facilitate the next steps of investigation as discussed below.

5.2 Case Management Dashboard

To provide an interactive approach to build and monitor case-series, we have designed the incident case management dashboard (Fig. 4) that provides the following features.

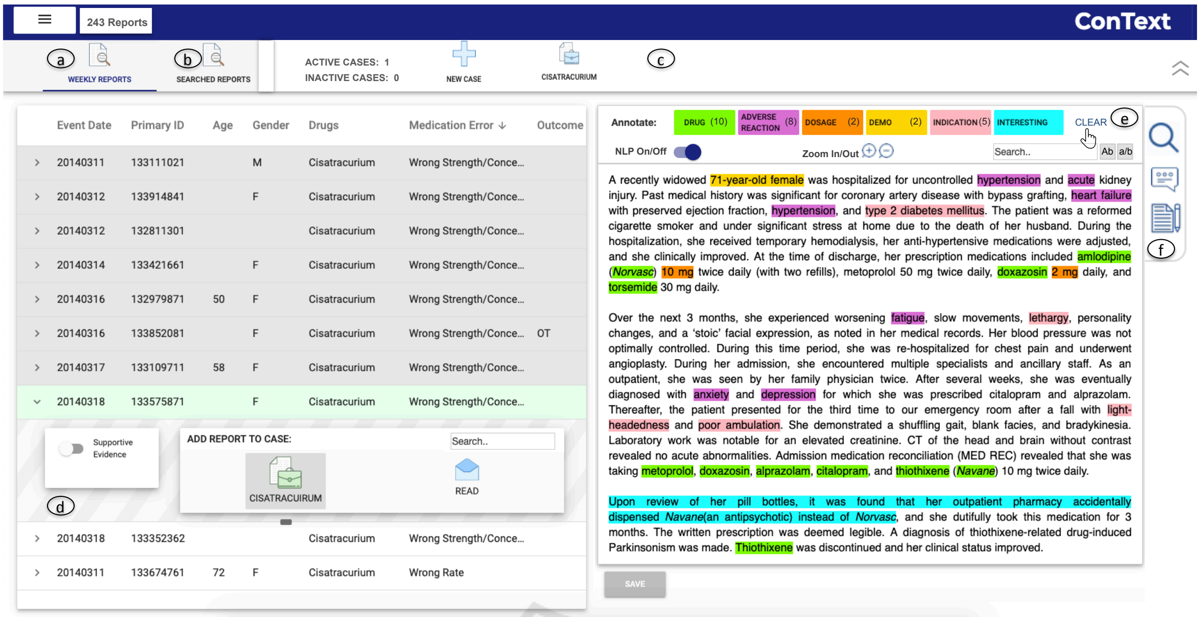
Case Creation. At any time during the analysis if an analyst considers a report important enough to open an investigation, ConText allows her to interactively create a case ((Fig. 2c) and add the report into the case ((Fig. 2d). The analyst can also select if a report is primary (strong evidential information) or supportive evidence (weak information) to the case (Fig. 2d).

Case Building. When a case is created, ConText recommends other reports with similar evidential information to assist the analyst in building a case. For this we leverage the keywords marked within the report, either using NLP or explicitly annotated by the analyst as they convey important information about the reports — therefore are conduits towards constructing descriptors of a case. These case descriptors are used to automatically recommend reports that are most similar to the reports within a a case. A similar approach is taken by Cheng et al. (Cheng and Gotz, 2009) to recommend relevant web pages based on user's notes. More advanced document recommendation techniques using word embeddings (Berger et al., 2016) can also be plugged into ConText.

An analyst can interactively update the domain-informed "recommendation query" by modifying the descriptors as well as operation (Fig. 3). We leverage the well-known *Okapi BM25* (Robertson et al., 2009) information retrieval model with the *inverted index* built upon incident reports to implement such recommendation (using Apache Lucene). The reports that match the query descriptors are ranked based on the proportion of the matched descriptors from the query represented as glyph (Fig. 4b).

Case Summary. ConText provides an overview of the reports collected within a case-series by displaying a summary of the key information including the phrases marked by the analyst during the analysis of the narratives (Fig. 4d). For the analysts annotations, we display each keyword as a bar with its length mapped to the frequency of the keyword. The count of reports associated with a keyword is also displayed to help analysts in composing their query.

An analyst can also view the distribution of the reports marked as strong and supportive evidence, along with the comments added to reports within a case. This helps the analyst to quickly review the



	Event Date	Primary ID	Age	Gender	Drugs	Medication Error ↓	Outcome
›	20140311	133111021		M	Cisatracurium	Wrong Strength/Conce...	
›	20140312	133914841		F	Cisatracurium	Wrong Strength/Conce...	
›	20140312	132811301			Cisatracurium	Wrong Strength/Conce...	
›	20140314	133421661		F	Cisatracurium	Wrong Strength/Conce...	
›	20140316	132979871	50	F	Cisatracurium	Wrong Strength/Conce...	
›	20140316	133852081		F	Cisatracurium	Wrong Strength/Conce...	OT
›	20140317	133109711	58	F	Cisatracurium	Wrong Strength/Conce...	
˅	20140318	133575871		F	Cisatracurium	Wrong Strength/Conce...	
›	20140318	133352362			Cisatracurium	Wrong Strength/Conce...	
›	20140311	133674761	72	F	Cisatracurium	Wrong Rate	

A recently widowed 71-year-old female was hospitalized for uncontrolled hypertension and acute kidney injury. Past medical history was significant for coronary artery disease with bypass grafting, heart failure with preserved ejection fraction, hypertension, and type 2 diabetes mellitus. The patient was a reformed cigarette smoker and under significant stress at home due to the death of her husband. During the hospitalization, she received temporary hemodialysis, her anti-hypertensive medications were adjusted, and she clinically improved. At the time of discharge, her prescription medications included amlodipine (*Norvasc*) 10 mg twice daily (with two refills), metoprolol 50 mg twice daily, doxazosin 2 mg daily, and torsemide 30 mg daily.

Over the next 3 months, she experienced worsening fatigue, slow movements, lethargy, personality changes, and a 'stoic' facial expression, as noted in her medical records. Her blood pressure was not optimally controlled. During this time period, she was re-hospitalized for chest pain and underwent angioplasty. During her admission, she encountered multiple specialists and ancillary staff. As an outpatient, she was seen by her family physician twice. After several weeks, she was eventually diagnosed with anxiety and depression for which she was prescribed citalopram and alprazolam. Thereafter, the patient presented for the third time to our emergency room after a fall with light-headedness and poor ambulation. She demonstrated a shuffling gait, blank facies, and bradykinesia. Laboratory work was notable for an elevated creatinine. CT of the head and brain without contrast revealed no acute abnormalities. Admission medication reconciliation (MED REC) revealed that she was taking metoprolol, doxazosin, alprazolam, citalopram, and thiothixene (*Navane*) 10 mg twice daily.

Upon review of her pill bottles, it was found that her outpatient pharmacy accidentally dispensed *Navane*(an antipsychotic) instead of *Norvasc*, and she dutifully took this medication for 3 months. The written prescription was deemed legible. A diagnosis of thiothixene-related drug-induced Parkinsonism was made. Thiothixene was discontinued and her clinical status improved.

Figure 2: The Incident Analysis View allows analyst to identify evidential reports with line-listing of reports on the left and Content Analysis Panel on the right. (a) Current weeks reports. (b) Panel to view searched reports. (c) The dashboard panel with active cases. (d) To add a report to a case. (e) Menu to correct and control the annotations in the narrative. (f) Option to search across the reports and creating notes on a report. Due to privacy concerns, a FAERS-like publicly available safety report narrative (Da Silva and Krishnamurthy, 2016) is shown in the Content Panel.

important details of their case especially when a case is open for a longer time.

Case Monitoring. An analyst might be working with many active cases, with some new and others older ones. Therefore, ConText provides an alerting feature to notify analysts about the arrival of new evidential reports that are relevant to any existing active case-series. Every week new reports are added to the existing unread reports, thus creating a new batch. When new reports are received that match an existing case-series in terms of the specified recommendation query, then analysts are alerted on their dashboard (Fig. 4e). By default the alert operation uses the case descriptors from the case summary to recommend the relevant reports. When desired, the analyst can customize the alert criteria by modifying the query (Fig. 3).

6 DEVELOPMENT PROCESS AND INSIGHTS

As previously mentioned, ConText is part of our over two years of collaboration with the FDA. In this section, we discuss some of the main steps of the design and development process during this period. Our goal is to highlight some of the challenges we faced during this time – this will be the basis for some

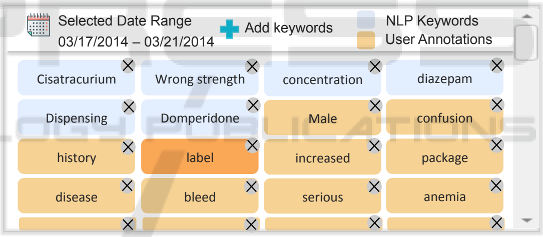


Figure 3: The Recommendation Query Panel with both NLP and user generated descriptors to allow analysts steer investigations by finding relevant evidential reports.

of the lessons we present in Section 8.

Though our design study does not explicitly follow the nine stages suggested by Sedlmair et al. Sedlmair et al. (2012), we did naturally progress through the main stages of the process. Due to our ongoing collaboration, we had observed that evidence collection and management were one of the core and most frequently performed tasks. Thus our first stage started with the *core phase* to discover and characterize the problem Sedlmair et al. (2012), that is, requirement analysis as discussed in Section 3.

During the *design phase*, we iteratively refined our designed features, visualizations and interface based on the feedback from the experts. As design alternatives, we presented sketches of tag-clouds with tf-idf and topic clusters using Latent Dirichlet

Allocation Blei et al. (2003) for report analysis. The experts, however, found these approaches suitable for someone unfamiliar with these reports to get general insights. Analysts instead emphasized on keeping the raw reports intact as they seek certain information within these reports for decision making. For the recommended documents our initial designs included 2D representations (tiles) of the most similar documents with score mapped to visual cues, but analysts wanted to access the actual report along with the score right away without additional mouse clicks (Fig. 4b).

During the *implement phase*, after ConText was developed and tested in lab for usability, we conducted a pilot test with these three experts, which highlighted a few usability issues as well as suggestions on improving ConText features. For instance, experts suggested to let analysts choose which keywords they want to use for search in the Recommendation Query, and allowing them to set a customized alert for case monitoring as the criteria for evidence might vary from incident to incident. Other suggestions included using visual cues to differentiate between NLP-based keywords and user annotations for efficient query editing. After including these features in the final version of ConText presented in Section 5, we evaluated the system by conducing case-studies and interviews with ten analysts that were not involved in the design process and discuss it in detail in Section 7. Finally, the insights we gained during the design and development of ConText in Section 8 corresponds to the *write* and *reflect* stages of writing design studies Sedlmair et al. (2012).

7 EVALUATING ConText FOR IIA IN PHARMACOVIGILANCE

To demonstrate the effectiveness of ConText for IIA, we conducted case studies (Lam et al., 2011) followed by semi-structured interviews with ten domain experts (˜20% of the workforce). These experts (9 females, 1 male, average age = 37.1 years) were drug safety analysts at the FDA. They were not involved in the design process of ConText and were familiar with basic visualizations such as bar charts.

These evaluation sessions were each 1.25 hour long. During the first 15 minutes, we demonstrated the ConText prototype to these experts. After getting familiar to ConText (˜10 minutes), we asked these experts to explore the system to perform IIA tasks by analyzing their reports set in a think-aloud manner for about 30 minutes, while the follow-up semi-structured interviews including a survey and discussions took approximately 20 minutes. The FAERS data from 2014 was used during the evaluation. We took notes and recorded their feedback during these sessions and later transcribed them for analysis.

7.1 Case Studies

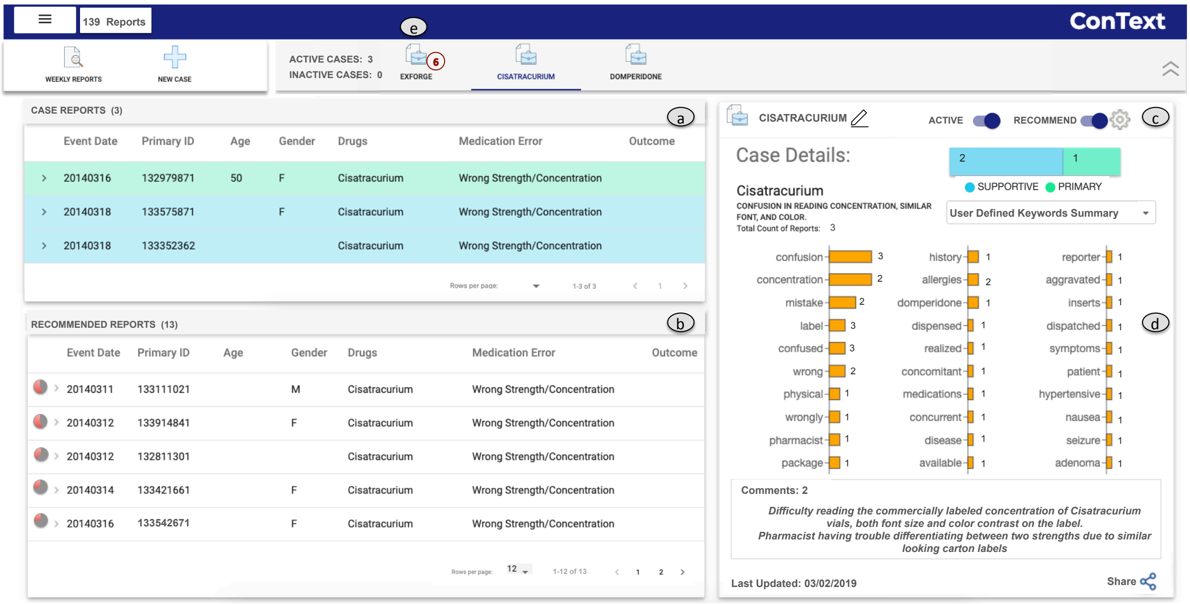
To illustrate the workflow of ConText and how it supports the Instance-based Incident Analysis (IIA) tasks, we only present the following case studies conducted with one of the analysts here due to space limitation. However, other analysts were able to derive similar findings. One of the analyst volunteered for follow-ups regarding the evidence alert feature of the system (illustrated below). The names of the analysts in these case studies are pseudo-anonymized.

Amy, a drug safety analyst responsible for medication error detection starts exploration of the reports using the Incident Analysis View (Fig. 2a). She has received 243 reports for this week that she needs to analyze one by one. From the line-listing, she observes that the drug ‘Cisatracurium’ is reported to have a serious outcome, thus she filters the reports for this drug and opens the narrative of the first report to read it (Fig. 2). The first thing she notices are the highlighted drug names and medication errors. She immediately reads the sentence that has the mention of the drugs. It says “Pharmacist called stating that they may be experiencing potency issues with Cisatracurium and Padilaxel, but they are not sure..”.

Skimming through the rest of the narrative, she comments “this narrative does not give much information about the incident, so i will not read it further”. She marks the report as ‘read’. It turns grey in the reports panel (Fig. 2-Left) to allow quick recognition of its ‘read’ state. She next opens the second narrative. While reading through the narrative, she finds the term ‘internal bleeding’ and highlights it using the interesting marking on the annotation menu (Fig. 2e). She marks the narrative as read, and adds the comment “insufficient information”.

She repeats the same process for the next five narratives and keeps highlighting the interesting words in each narrative and adds comments where needed. She states, “this is our routine, most of the reports are false alarms and usually don’t get investigated further”.

For the next report’s narrative, she reads the sentence “several ICU nurses were having difficulty in reading the commercially labeled concentration of Cisatracurium vials” with ‘Cisatracurium’ highlighted. She says, “Cisatracurium is a muscle



CASE REPORTS (3)

	Event Date	Primary ID	Age	Gender	Drugs	Medication Error	Outcome
›	20140316	132979871	50	F	Cisatracurium	Wrong Strength/Concentration	
›	20140318	133575871		F	Cisatracurium	Wrong Strength/Concentration	
›	20140318	133352362			Cisatracurium	Wrong Strength/Concentration	

Rows per page: 1-3 of 3 ‹ 1 ›

RECOMMENDED REPORTS (13)

	Event Date	Primary ID	Age	Gender	Drugs	Medication Error	Outcome
›	20140311	133111021		M	Cisatracurium	Wrong Strength/Concentration	
›	20140312	133914841		F	Cisatracurium	Wrong Strength/Concentration	
›	20140312	132811301			Cisatracurium	Wrong Strength/Concentration	
›	20140314	133421661		F	Cisatracurium	Wrong Strength/Concentration	
›	20140316	133542671		F	Cisatracurium	Wrong Strength/Concentration	

Rows per page: 12 1-12 of 13 ‹ 1 2 ›

Case Details:

Cisatracurium
CONFUSION IN READING CONCENTRATION, SIMILAR FONT, AND COLOR.
Total Count of Reports: 3

Comments: 2

Difficulty reading the commercially labeled concentration of Cisatracurium vials, both font size and color contrast on the label.
Pharmacist having trouble differentiating between two strengths due to similar looking carton labels

Last Updated: 03/02/2019

Figure 4: Dashboard view for the Case ‘Cisatracurium’. (a) Reports within the case. (b) Recommended reports for the case. (c) Controls for recommendation query. (d) Case summary. (e) Alert of getting new evidential reports for the case Exforge.

paralyzing agent used on patients before surgery, if the concentration is mistaken then it can have critical health consequences”. She is now suspicious and is reading the full narrative from start to end. As she is reading, she highlights other phrases of interest to her. She seems interested in this narrative and explains, “this narrative can be describing a potential medication error with the drug Cisatracurium having similar labels for different concentrations” (**T1**). She adds “Difficulty reading the commercially labeled concentration of Cisatracurium vials, both font size and color contrast on the label” as a summary of the narrative by clicking on the comment button on the Content Analysis view (Fig. 2f). She clicks on the ‘Create New Case’ icon (Fig. 2c) and names it ‘Cisatracurium’ and add the description. By clicking the case name, she includes the report in this case as strong evidence (Fig. 2d). She can see the details of this newly created case in the dashboard (Fig. 4).

She now investigates if there are other evidential reports in the database with similar characteristics. She clicks on the “recommendation setting” button (Fig. 4c) and uses the default option of selecting all keywords in the query (Fig. 3). In a few seconds, she sees 13 reports in the recommended reports panel (Fig. 4b) that match the search criteria which she needs to investigate further one by one (**T2**).

She repeats the same process the next two weeks. At that time, she has identified two new reports for this case. She also has created two more cases ‘Domperidone’ and ‘Exforge’ through her findings during these past two weeks. She again is curious about the reports inside the ‘Cisatracurium’ case. By clicking on her ‘Cisatracurium’ case under her list of active cases (Fig. 4), she reads the description and remembers that this case was about some confusion in reading different concentrations of Cisatracurium. She also sees on the summary panel, that one of the three reports is a strong evidence while two are supportive.

Now, she is curious about the most important keywords in this case that she has been marking during her analysis. Using the drop-down menu (Fig. 4d), she selects “User-defined keywords” and sees a distribution of the most frequently words marked by her. She observes that the most frequent terms in all these cases are “confusion” and “concentration”. Reading through the comments, she says “I remember, these reports were talking about confusion in reading the concentration information”. She now goes back to her routine report analysis.

Case Monitoring. One week later, when Amy logs into ConText, she gets a notification of six newly received reports on her ‘Exforge’ case in her dashboard (Fig. 4e). She opens the case and sees the list of recommended reports (**T3**). Upon skimming their narratives one by one, she comments “Although these reports discuss issues with Exforge, none of these reports however have sufficient information, so I will just mark them as read”. Amy then proceeds to this week’s routine analysis. At any time during her analysis, she can go back to investigate a particular case.

In this way, ConText allows Amy to efficiently perform her IIA tasks in identifying evidential information within the reports, guiding her towards further evidence to build and monitor multiple investigations.

7.2 Expert Interviews

As part of the evaluation, after the aforementioned case-studies, we conducted semi-structured interviews with these 10 experts to get further feedback on the strengths and weaknesses of the system. We asked participants to rate the importance of ConText's main features on a 5 point likert-scale, and discuss the reasons for their importance. Overall, the feedback was encouraging. Fig. 5 depicts the features that were considered the most important for the workflow by the majority of our participants (avg rating > 3.0). From Fig. 5 we see that 'analysts annotations' supported by current tools is comparatively rated lower than the novel features that are not supported.

Justifications for the lower ratings (3-score) provided by the majority of participants included concerns about the accuracy of the computational techniques, that is, recommending the relevant evidence and identifying key information within the narratives using NLP. One participant mentioned "The highlights in the text [pointing towards NLP-generated access points] were not always correct, an adverse reaction was highlighted as an indication. It would be great if these mistakes are not that often". Four participants mentioned that if the system consistently guides them towards the true evidential reports, then they would trust these features and ConText would be beneficial for their tasks. Other minor features including 'marking a report strong or supportive evidence' and 'being able to search within the narrative' received an average rating of < 2.3.

Analysts evidently considered the main features of the system to be important for their IIA workflow. Regarding the highly rated features (Q2), some of analysts comments are summarized next. P3: "Sometimes these reports are very lengthy and looking for a drug or error can be tedious. This (domain-informed access points) can save us a lot of time" (**DG1**). P6: "Currently, we have to check our list of monitored drugs and match it with current reports to see if we have got a new report, or rely on our memory. Having an alert system that notifies us about new possibly relevant reports can be helpful" (**DG3**). P10: "Searching for reports that are similar in content is very hectic currently, the recommend functionality can make our lives easier" (**DG2**). In short, analysts had positive feedback and were excited about a ConText-like unified tool to assist them in their IIA tasks.

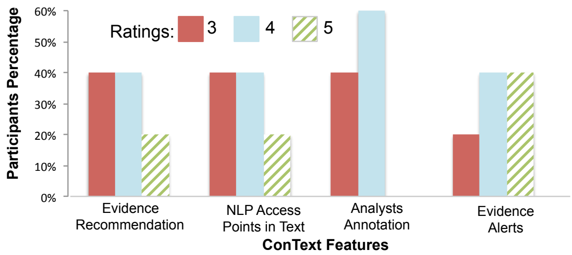


Figure 5: Participants feedback (ratings) on the importance of features. Ratings are at 5-point likert scale (1=least important, 5=most important.

Limitations in the current prototype were also recorded. In particular, few participants suggested more transparent visual query functions, such as interactive ways of building logical and/or queries. Others suggested to use visual cues to distinguish their commented 'read' reports from the uncommented ones to easily identify them.

8 DISCUSSION

ConText is designed to support the IIA workflow to identify issues and collect and manage evidence for Pharmacovigilance, a large domain world-wide (Jeetu and Anusha, 2010) having analytics goals and challenges (Bergvall et al., 2014) similar to the FDA. Our evaluation illustrates that systems like ConText can help fill the gap in the IIA workflow for investigating potentially life-critical incident reports which can also be adapted by other IIA domains such as the FAA.

We learned many lessons during the design and evaluation of ConText that we believe can be useful to the visualization and HCI community. These lessons come from our experience of developing a unified tool for the IIA and some comments and suggestions we received from the FDA experts. Below we discuss these lessons that include both new insights we deem useful for the design of future systems for IIA (L1, L3, L5) as well as some established knowledge we intend to corroborate with additional details and further support for their value (L2, L4).

L1. Actual Text Reports Are the Backbone of IIA. During the initial interviews, we observed that analysts continuously emphasized the importance of reading the actual text narratives to make a decision if a reported incident is worthy of opening an investigation. The importance of reading the actual text document is highlighted previously in other investigative domains as well (Görg et al., 2014). Our initial designs included 2D document representations for the recommended documents. Analysts wanted to see the document first hand without having to click through the 2D tile (abstraction). Existing work to aid actual documents with visualizations, without disrupting the raw text, is limited to typographic features such as highlighting (Strobelt et al., 2015). Other text analytics approaches provide summaries and abstractions of text documents, such as clustering, or topic analysis (Jänicke et al., 2015). We propose that adding a layer of such abstraction to these text reports (Koch et al., 2014) would need careful design and empirical evaluation to examine if the abstraction improves or worsens the efficiency of the IIA workflow, because analysts have to read the narrative in any case.

L2. Goal-oriented Analysis Outweighs General Insight Seeking. During the initial design phase of the project, we discussed sketches of designs consisting word clouds and topic analysis (Blei et al., 2003) – common visual document analysis approaches – to help analysts examine the incident reports and get insights about these reports. The insights from these techniques were general (unique or similar keywords/topics) and were not helpful in making a decision whether a certain report is indicative of a potential problem. The analysts instead emphasized on the importance of certain information within these reports for decision making. This was confirmed during evaluation as well when analysts would first read the sentences with highlighted NLP-generated access points, paying attention to specific information such as drug and treatment. While insight generation is one of the main metrics for evaluating visual analytics (North, 2006), it's important that such insights are aligned with the analysts goals, which we have witnessed during the development of ConText. Therefore, for more focused tasks such as IIA, analysis goals should be prioritized over general insight seeking during design.

L3. Smooth Transition between Concurrent Investigative Tasks Is Important. During evaluation, we observed that analysts often switched between analysing their weekly batch and collecting evidence for a particular problem they found interesting while reviewing a narrative. One analyst, in particular, spotted a report indicative of an adverse reaction from the reports recommended for a potential medication error and started investigating it by creating a new case. In short, analysts do not review reports in a linear fashion, and ends up going in multiple directions based on their findings, which ConText supports. During evaluation, analysts also mentioned that sometimes they lag behind their weekly reports analysis due to an active and time-intensive investigation of an ongoing safety problem. Therefore, it is crucial for future designs to keep track of the state of multiple analyses at all times by providing occasional reminders about their incomplete tasks, so that they can easily pick up where they left off an analysis.

L4. Providing Support for Tracking Analysts' Operations Leading to Insights. When analysts were performing IIA tasks during our evaluation, several analysts pointed out the need for the system to remember their queries used during searching for evidence. Particularly, upon the confirmation of a report being evidence to a suspected problem, the analysts want to use the same search query possibly with minor modifications, for future searches to collect evidence for a certain case. Given the importance of analytics provenance (North et al., 2011), future designs for IIA systems can incorporate analysts' interactions with the system similar to (Endert et al., 2015), to allow analysts quickly access their reasoning process that lead to the insights in the first place.

L5. Communicating Uncertainty to Promote Transparency Is Crucial. During our evaluation, we observed that participants were hesitant to trust the results of computational techniques such as NLP or recommended evidence because they are used to manually analyzing actual report text. Due to ambiguity in the medical text, NLP techniques suffer from lower accuracy (Jackson et al., 2017; Wunnava et al., 2020) and hence leading to uncertainty in the data (Mayr et al., 2019). Besides developing more accurate algorithms, one way to to address this is to design systems that visually communicate the uncertainty in the underlying data to build users' trust. For instance, similar to (Kay et al., 2016), a word-scale visualization (Goffin et al., 2020) can be used with each NLP-generated entity depicting the confidence interval for the model accuracy. However, this would need to be empirically investigated in the context of IIA.

9 CONCLUSION

In this paper, we contribute a design study for an analytics prototype ConText to support the Instance-based Incident Analysis (IIA). Our design of interactive operations and features is based on an in-depth analysis of the Pharmacovigilance workflows at the US FDA. ConText is designed as a unified system to support the identification of an incident of concern, finding evidence to build and strengthen a case supporting the incident, and interactively managing multiple ongoing cases over a large weekly batch of semi-structured text reports. We discuss our experience of designing and evaluating ConText, and share the insights we gained during this process to benefit future IIA tools and techniques for this and similar real-world problems concerning public safety.

ConText prototype, developed as a proof of concept for designing visual analytics for IIA, has impacted and inspired the next generation of commercial tools being developed for IIA at the FDA. In the future we plan to empirically study the long-term usability of ConText in performing IIA tasks. This would give us further insights into the adoption of an interactive analytics tool such as ConText in life-critical workflows. Other research directions include designing and evaluating interactive trustworthy visual displays for analyzing textual data (Mayr et al., 2019).

REFERENCES

Allahyari, M., Pouriyeh, S., et al. (2017). A brief survey of text mining: Classification, clustering and extraction techniques. *arXiv preprint arXiv:1707.02919*.

Amershi, S., Lee, B., Kapoor, A., Mahajan, R., and Christian, B. (2011). CueT: human-guided fast and accurate network alarm triage. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*, pages 157–166.

Avnon, Y. and Boggan, S. L. (2010). Fit and finish using a bug tracking system: challenges and recommendations. In *CHI'10 Extended Abstracts on Human Factors in Computing Systems*, pages 4717–4720. ACM.

Berger, M., McDonough, K., and Seversky, L. M. (2016). cite2vec: Citation-driven document exploration via word embeddings. *IEEE Transactions on Visualization and Computer Graphics*, 23(1):691–700.

Bergvall, T., Norén, G. N., and Lindquist, M. (2014). vigigrade: a tool to identify well-documented individual case reports and highlight systematic data quality issues. *Drug Safety*, 37(1):65–77.

BIFACT (2019). http://www.bifact.com/faers-bifact.html [Accessed: 2019-06-19].

Blei, D. M., Ng, A. Y., and Jordan, M. I. (2003). Latent dirichlet allocation. *Journal of Machine Learning Research*, 3(Jan):993–1022.

Böhm, R., von Hehn, L., Herdegen, T., Klein, H.-J., Bruhn, O., Petri, H., and Höcker, J. (2016). Openvigil fda–inspection of us american adverse drug events pharmacovigilance data and novel clinical applications. *PloS one*, 11(6):e0157753.

CFPB (2021). https://www.consumerfinance.gov/ [Accessed: 2021-12-01].

Chen, Y., Barlowe, S., and Yang, J. (2010). Click2annotate: Automated insight externalization with rich semantics. In *IEEE Symposium on Visual Analytics Science and Technology (VAST)*, pages 155–162. IEEE.

Cheng, W.-H. and Gotz, D. (2009). Context-based page unit recommendation for web-based sensemaking tasks. In *Proceedings of the 14th International Conference on Intelligent User Interfaces (IUI)*, pages 107–116. ACM.

Da Silva, B. A. and Krishnamurthy, M. (2016). The alarming reality of medication error: a patient case and review of pennsylvania and national data. *Journal of Community Hospital Internal Medicine Perspectives*, 6(4):31758.

Endert, A., Chang, R., North, C., and Zhou, M. (2015). Semantic interaction: Coupling cognition and computation through usable interactive analytics. *IEEE Computer Graphics and Applications*, 35(4):94–99.

FDA (2018). https://www.fda.gov/ICECI/CriminalInvesti\ \gations/ucm594800.htm[Accessed: 2018-02-10].

FDA (2021). www.fda.gov/Drugs/GuidanceCompliance\ \RegulatoryInformation/Surveillance/AdverseDrug\ \Effects/ucm070434.htm [Accessed: 2021-02-10].

Goffin, P., Blascheck, T., Isenberg, P., and Willett, W. (2020). Interaction techniques for visual exploration using embedded word-scale visualizations. In *Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems*, pages 1–13.

Görg, C., Liu, Z., Kihm, J., Choo, J., Park, H., and Stasko, J. (2013). Combining computational analyses and interactive visualization for document exploration and sensemaking in jigsaw. *IEEE Transactions on Visualization and Computer Graphics*, 19(10):1646–1663.

Görg, C., Liu, Z., and Stasko, J. (2014). Reflections on the evolution of the jigsaw visual analytics system. *Information Visualization*, 13(4):336–345.

Gotz, D., Zhou, M. X., and Aggarwal, V. (2006). Interactive visual synthesis of analytic knowledge. In *IEEE Symposium On Visual Analytics Science And Technology*, pages 51–58. IEEE.

Härmark, L. and Van Grootheest, A. (2008). Pharmacovigilance: methods, recent developments and future perspectives. *European Journal of Clinical Pharmacology*, 64(8):743–752.

Jackson, R. G., Patel, R., et al. (2017). Natural language processing to extract symptoms of severe mental illness from clinical text: the clinical record interactive search comprehensive data extraction project. *BMJ open*, 7(1).

Jänicke, S., Franzini, G., Cheema, M. F., and Scheuermann, G. (2015). On close and distant reading in digital humanities: A survey and future challenges. In *Eurographics Conference on Visualization (EuroVis)-STARs. The Eurographics Association*.

Jeetu, G. and Anusha, G. (2010). Pharmacovigilance: a worldwide master key for drug safety monitoring. *Journal of Young Pharmacists*, 2(3):315–320.

Jian-Xiang, W., Yun-Xia, Z., et al. (2015). ADRVis: an information visualization platform for adverse drug reactions. *International Journal of u-and e-Service, Science and Technology*, 8(10):139–150.

Kakar, T., Qin, X., et al. (2019a). Mev: Visual analytics for medication error detection. In *International Conference on Information Visualization Theory and Applications (IVAPP)*. SciTePress.

Kakar, T., Qin, X., Rundensteiner, E., Harrison, L., Sahoo, S., and De, S. (2019b). Diva: Exploration and validation of hypothesized drug-drug interactions. In *Computer Graphics Forum*, volume 38, pages 95–106. Wiley Online Library.

Karimi, S., Wang, C., Metke-Jimenez, A., Gaire, R., and Paris, C. (2015). Text and data mining techniques in adverse drug reaction detection. *ACM Computing Surveys (CSUR)*, 47(4):56.

Kay, M., Kola, T., et al. (2016). When (ish) is my bus? user-centered visualizations of uncertainty in everyday, mobile predictive systems. In *Proceedings of the 2016 CHI Conference on Human Factors in Computing Systems*, pages 5092–5103.

Koch, S., John, M., Wörner, M., Müller, A., and Ertl, T. (2014). Varifocalreader—in-depth visual analysis of large text documents. *IEEE Transactions on Visualization and Computer Graphics*, 20(12):1723–1732.

Lam, H., Bertini, E., Isenberg, P., Plaisant, C., and Carpendale, S. (2011). Empirical studies in information visualization: Seven scenarios. *IEEE Transactions on Visualization and Computer Graphics*, 18(9).

Lazarou, J., Pomeranz, B. H., and Corey, P. N. (1998). Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *The Journal of American Medical Association*, 279(15):1200–1205.

Liu, S., Wang, X., Collins, C., Dou, W., Ouyang, F., El-Assady, M., Jiang, L., and Keim, D. (2018). Bridging text visualization and mining: A task-driven survey. *IEEE Transactions on Visualization and Computer Graphics*.

Liu, Z., Görg, C., Kihm, J., Lee, H., Choo, J., Park, H., and Stasko, J. (2010). Data ingestion and evidence marshalling in jigsaw vast 2010 mini challenge 1 award: Good support for data ingest. In *IEEE Conference on Visual Analytics Science and Technology (VAST)*, pages 271–272. IEEE.

Marais, K. B. and Robichaud, M. R. (2012). Analysis of trends in aviation maintenance risk: An empirical approach. *Reliability Engineering & System Safety*, 106:104–118.

Mayr, E., Hynek, N., Salisu, S., and Windhager, F. (2019). Trust in information visualization. In *EuroVis Workshop on Trustworthy Visualization (TrustVis)*, volume 20191187.

North, C. (2006). Toward measuring visualization insight. *IEEE Computer Graphics and Applications*, 26(3).

North, C., Chang, R., Endert, A., Dou, W., May, R., Pike, B., and Fink, G. (2011). Analytic provenance: process+ interaction+ insight. In *CHI'11 Extended Abstracts on Human Factors in Computing Systems*, pages 33–36.

Robertson, S., Zaragoza, H., et al. (2009). The probabilistic relevance framework: Bm25 and beyond. *Foundations and Trends® in Information Retrieval*, 3(4).

SDR (2021). http://av-info.faa.gov/sdrx/ [Accessed: 2021-11-30].

Sedlmair, M., Meyer, M., and Munzner, T. (2012). Design study methodology: Reflections from the trenches and the stacks. *IEEE Transactions on Visualization and Computer Graphics*, 18(12):2431–2440.

Serrano, N. and Ciordia, I. (2005). Bugzilla, itracker, and other bug trackers. *IEEE Software*, 22(2):11–13.

Shneiderman, B., Plaisant, C., and Hesse, B. W. (2013). Improving healthcare with interactive visualization. *Computer*, 46(5):58–66.

Shrinivasan, Y. B., Gotzy, D., and Lu, J. (2009). Connecting the dots in visual analysis. In *IEEE Symposium on Visual Analytics Science and Technology*, pages 123–130. IEEE.

Stasko, J., Görg, C., and Liu, Z. (2008). Sensemaking across text documents: human-centered, visual exploration with jigsaw. In *Sensemaking Workshop@ CHI 2008*.

Strobelt, H., Oelke, D., Kwon, B. C., Schreck, T., and Pfister, H. (2015). Guidelines for effective usage of text highlighting techniques. *IEEE Transactions on Visualization and Computer Graphics*, 22(1):489–498.

Sultanum, N., Singh, D., Brudno, M., and Chevalier, F. (2018). Doccurate: A curation-based approach for clinical text visualization. *IEEE Transactions on Visualization and Computer Graphics*, 25(1):142–151.

Wright, W., Schroh, D., Proulx, P., Skaburskis, A., and Cort, B. (2006). The sandbox for analysis: concepts and methods. In *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*, pages 801–810. ACM.

Wunnava, S., Qin, X., et al. (2017). Towards transforming fda adverse event narratives into actionable structured data for improved pharmacovigilance. In *Proceedings of the Symposium on Applied Computing*, pages 777–782. ACM.

Wunnava, S., Qin, X., Kakar, T., Kong, X., and Rundensteiner, E. (2020). A dual-attention network for joint named entity recognition and sentence classification of adverse drug events. In *Proceedings of the 2020 Conference on Empirical Methods in Natural Language Processing: Findings*, pages 3414–3423.