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White Paper

De-risking Your Bots: Adverse Event Detection with Conversational AI

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Many pharmaceutical companies have recently adopted virtual health assistants and chatbots to engage and support patients and healthcare providers (HCPs) with education on treatments, products, and protocols, identification of cost and coverage resources, and personalized support to improve medication adherence and outcomes.

The use of these types of conversational digital tools presents patients and healthcare providers with an increasingly preferred method of engagement to quickly convey and respond to relevant information. The recent increased usage of virtual health assistants has introduced new risks and **a new category of need for better adverse event detection and reporting**.

The process of detecting, confirming, and escalating medication-induced adverse events is burdensome and costly for pharma companies, which heavily rely on manual identification and reporting of adverse events from healthcare providers and patients. Not all patients may recognize symptoms as a medication-induced adverse event— and need support in understanding this and available options for reporting adverse events.

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Implications Around Adverse Events

Adverse events account for more than 100,000 deaths per year in the United States, representing the fourth leading cause of death after heart disease, cancer and stroke, but well ahead of diabetes, pulmonary diseases and AIDS.[1]

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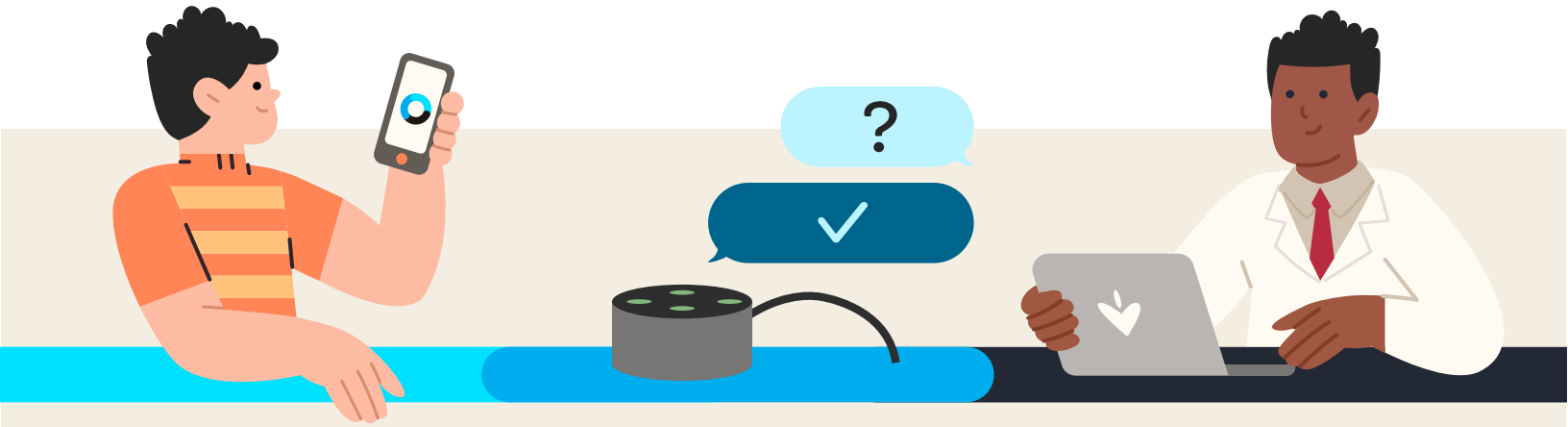
The overall number of adverse drug events reported in the FAERS database is steadily increasing, and mandatory reports submitted by manufacturers of biopharmaceutical drugs and medical devices account for most of this increase. Various industry studies estimate that the volume of adverse events managed by manufacturers is increasing by at least 18% each year. Still, it is estimated that only 1-10% of all adverse events that occur are ever submitted as a report to the Food and Drug Administration (FDA).[2]

From these reports, the FDA may update a product's labeling information, restrict the use of the drug, communicate new safety information to the public, or, in rare cases, remove a product from the market.[3] These measures can help reduce preventable adverse events (PAES).

In the U.S., over 250,000 patients who receive medical care each year experience an adverse event.[4] An analysis review found a median annual incidence of adverse events of 9.2%, among which nearly half were found to be preventable.[5]

The FDA and Department of Justice (DOJ) take adverse event reporting obligations seriously and do not view them simply as technical regulatory requirements. In December 2020, The Lancet published a study reviewing very serious adverse event reactions between 1997 and 2019 identified by clinicians. In this study, 20 very serious adverse event reactions involved 15 drugs and one device— and legal settlements totaled $38.4 billion for 753,900 injured persons.[6]

Chatbots are an increasingly popular tool for pharmaceutical brand marketing and patient support, but few are equipped to accurately flag when a patient is having a medication-induced side effect. This can hinder pharmacovigilance processes and success. Orbita's Adverse Event Detection module integrates with existing chat services to accurately detect and seamlessly assist users in escalating adverse reactions to medications, ultimately improving the efficiency and timeliness of adverse event monitoring.



Educate Users

Educate users about possible adverse events at the moment of detection within chat interactions.

Augment Call Centers

Enhance efficiency of existing call center operations with timely, more accurate information about potential events.

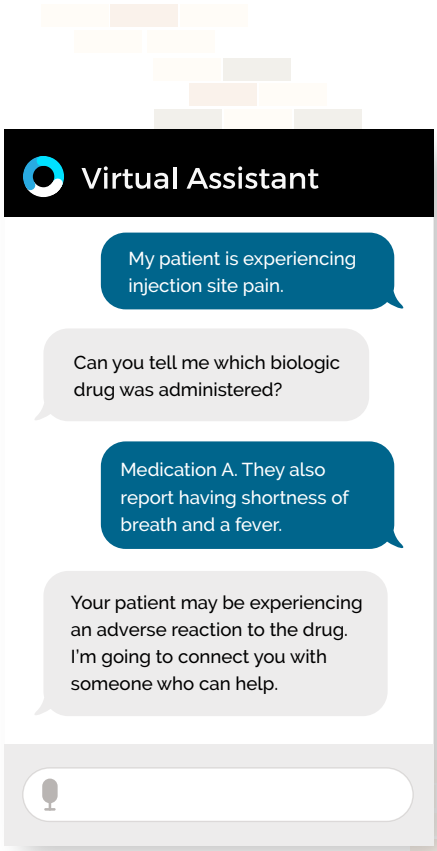
Improve Pharmacovigilance

Ensure compliance of chatbot applications with pharmacovigilance requirements for detection, collection, monitoring, and escalation of adverse events.

Equipping Conversational AI to Detect Adverse Events

Until now, ordinary chatbots available on the market have offered drug manufacturers limited visibility because they do not have the ability to detect an adverse event in the context of a conversational experience with patients and/or HCPs. Without this detection capability, drug manufacturers run the risk of not responding to adverse events appropriately.

As a relatively new channel in the pharmaceuticals and life sciences space, **conversational AI technology goes beyond ordinary chatbots to power intelligent virtual health assistants that can distinguish and take action on patient utterances within a dialogue**— by leveraging machine learning and natural language processing capabilities. An example of this is how a conversational AI-powered virtual assistant can detect, confirm, and appropriately escalate adverse events through conversational experiences with patients and HCPs. Not to mention, invaluable analytics around adverse events (collected through these interactions with patients and HCPs) support efforts in future research and treatment— and help identify gaps in the patient journey to proactively manage potential challenges in the future.



While conversational AI platforms draw from a robust corpus of medical and conversational data, the machine learning aspect continually improves the platform's accuracy with continued usage. Virtual assistants powered by a conversational AI platform are omnichannel and multi-modal, enabling them to engage patients and HCPs where they are across different channels and modalities, such as a pharmaceutical brand's website, social media, SMS, IVR, and more.

Orbita Adverse Event Detection Module, Empowered by Conversational AI

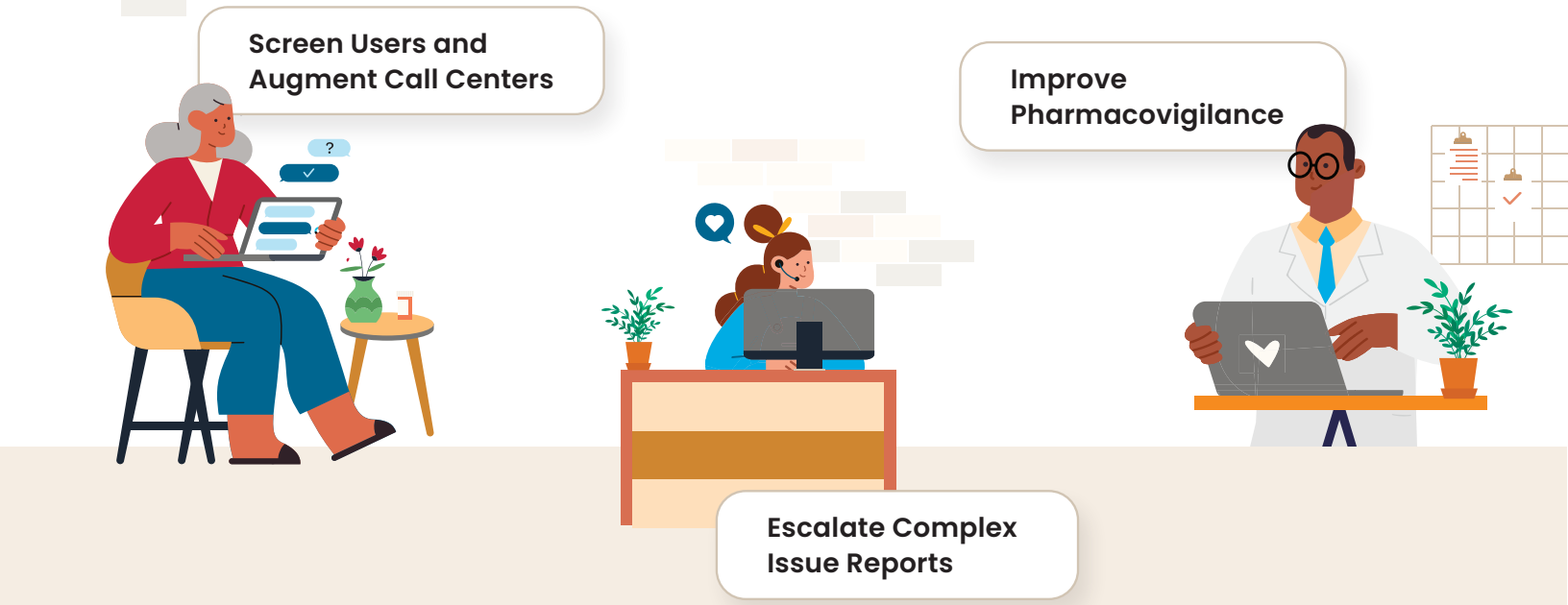
In late 2020, Orbita expanded the capabilities of its conversational AI platform by devising a model to detect adverse events— resulting in what is now called the **Orbita Adverse Event Detection module.**

This new module integrates with existing conversational solutions to improve user experiences for patients and HCPs across their preferred channel, augment call centers, and support pharmacovigilance efforts. By leveraging machine learning to analyze all free utterances that take place in conversational experiences with virtual assistants, the module is able to distinguish statements containing or indicating the presence of an adverse event.

Accuracy and Reliability

The Orbita Adverse Event Detection module is 99% accurate at detecting adverse events. Testing of this module has shown a recall score of nearly 100% (recall— also known as the probability of detection—is a metric reflecting a model's ability to correctly classify an event such as an utterance while taking the model's miss rate into account).

The conversational design and flow of this module ensures that users are appropriately directed to the correct resource or service that they need. Once an adverse event is detected and confirmed in the context of a conversational interaction, the designated escalation flow is triggered: a transcript is automatically populated and exported to the drug manufacturer, who then uses it to compile a comprehensive report for the FDA.



Capabilities and Benefits of Integrating Adverse Event Detection into Conversational AI

- **Modern application programming** interface to quickly integrate with existing chatbot and voice solutions
- **Secure infrastructure to** ensure safety and privacy of user data
- **Flexible escalation logic** to support efficient routing and compliant reporting of complex issues including product complaints
- **Advanced machine learning** to ensure accurate adverse event detection

Supporting and Empowering Patients

With 24/7, on-demand access, patients can continue using a virtual assistant as a resource to easily access educational information and other support resources on medications and treatments.

With Orbita's new Adverse Event Detection feature, the virtual assistant can distinguish utterances of adverse events within the dialogue with the patient, such as *"I have a rash at the injection site"* and *"Does this medication cause a rash at the injection site?"*

This module automatically populates a transcript of the report and exports it to the pharma company to compile a comprehensive FDA report.

After detection of an adverse event, the designated escalation flow is triggered. The virtual assistant will offer support and supplemental resources to overcome or reduce the symptoms, even connecting the patient to a live representative if necessary. This increases the likelihood of medication adherence among patients, improving outcomes and further empowering patients in their care journeys.

Supporting and Educating HCPs

As HCPs engage with a virtual assistant for medication information and educational resources, they can easily and quickly report and provide feedback on adverse events through Orbita's new Adverse Event Detection module.

Let's say a rheumatologist has questions about the new medication that his arthritic patient is taking. Instead of scanning through search engines and digging through websites, a virtual assistant greets the provider upon arrival on the dedicated medication website. At this point, the provider is guided to the specific drug information they seek about administration, dosing, storage, safety, and more. Not only does this provide information to providers on the fly but can give back valuable face time with patients during appointments that might have been spent looking for answers otherwise.

During the example conversation described above, the rheumatologist could say, "*My patient is experiencing injection site pain*" or "*My patient has a rash at the injection site.*"

The virtual assistant can now differentiate these phrases as adverse events from other general inquiries such as *"Does this medication cause a rash at the injection site?"*

Once an adverse event has been detected, it is automatically transcribed and exported to the pharmaceutical company to help populate a report sent to the FDA.

Key Takeaways

With the ability to automate the detection of adverse events, pharmaceuticals and life sciences companies can create and foster more meaningful user experiences for patients and HCPs where they are through their preferred communication channels and decrease risks around missing adverse events. With this automation, drug manufacturers will be able to:

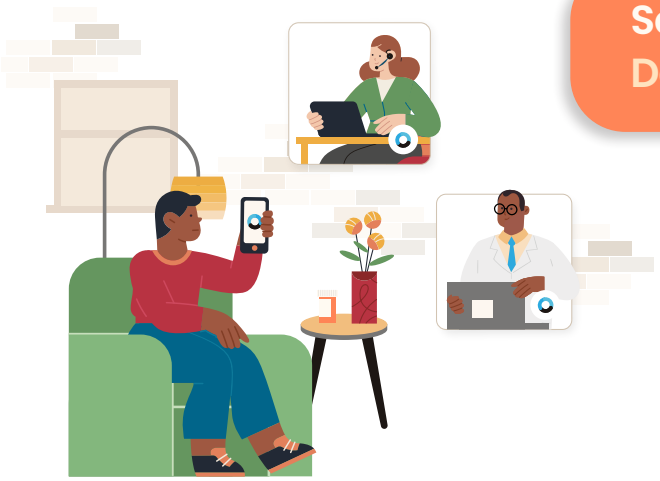
- Enhance timeliness and accuracy of reporting adverse events
- Enrich engagements with patients and HCPs in digital forums
- Improve research with insights from predictive analytics
- Reduce costs associated with manual processes and outsourcing

Learn how your organization can:

- **Educate users about possible adverse events at the moment of detection within chat interactions**
- **Enhance efficiency of existing call center operations with timely, more accurate information about potential adverse events**
- **Ensure compliance of chatbot applications with pharmacovigilance requirements for detection, collection, monitoring, and escalation of adverse events**

About Orbita

Orbita's award-winning, HIPAA-compliant conversational AI platform powers voice and chat solutions for healthcare and life sciences organizations that improve patient engagement, increase clinical efficiency, and improve outcomes. Customers include innovative organizations like Mass General Brigham, Mayo Clinic, Amwell, Yale New Haven Hospital, Cancer Treatment Centers of America, University of Chicago Medicine, and a portfolio of pharmaceutical clients. Partners include Cognizant, Deloitte, Pariveda, and ServiceNow.



See Orbita's Adverse Event Detection Module in action

Request a demo →

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