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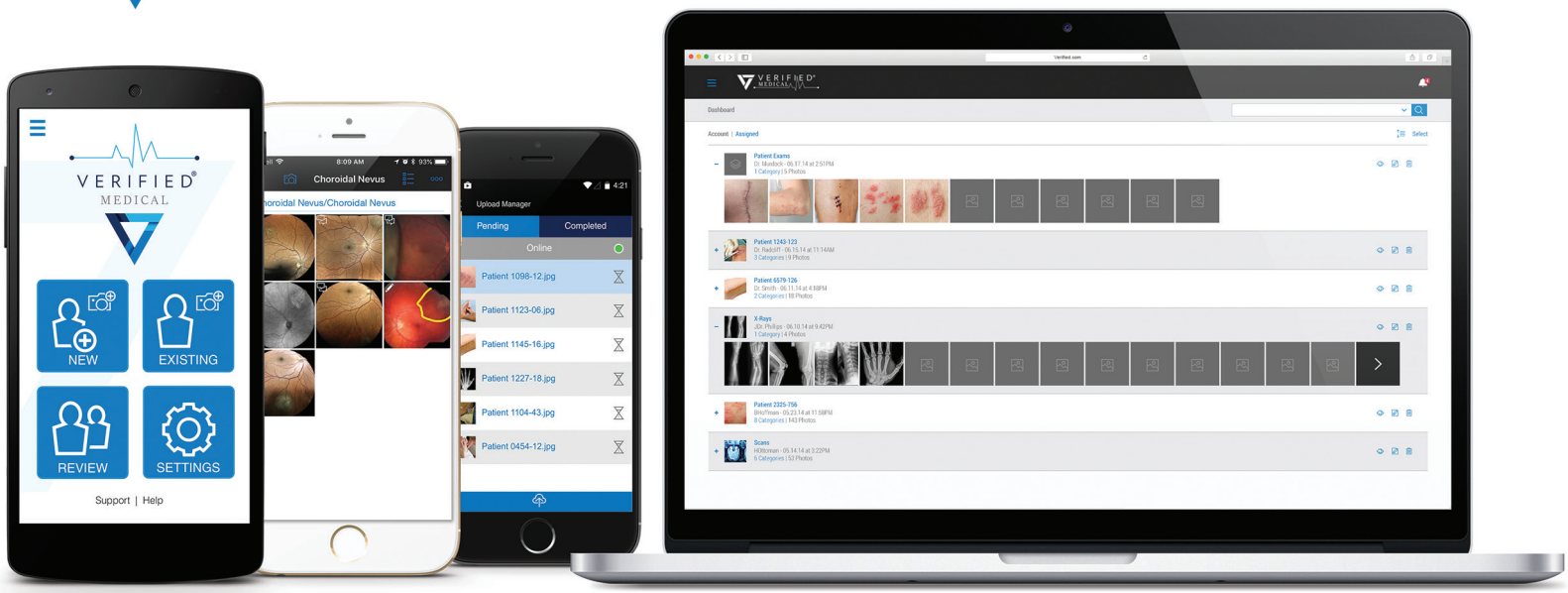

Verified Medical Ophthalmology Pharmacovigilance Pilot Project

In October 2017, Verified Network Inc. launched a three month pilot project with a major pharmaceutical manufacturer in Canada. The primary objective was to investigate how the Verified Medical platform would assist in detecting and reporting adverse effects for a leading ophthalmology drug. The pilot team consisted of leading Ophthalmologists and Optometrists, each chosen for their expertise in detecting retinal issues and understanding of technology and the role in the Ophthalmology space, coordinated with a leading retinal specialist.

Scope and Goals

Verified Medical was used to securely capture and store patient images and data, with metadata to identify patients that exhibited an adverse effect following application of the drug. Through secure accounts, the team uploaded Fundus images and scans to the platform to collaborate with their peers the retinal specialist, identifying potential adverse effects of treatment and automatically generating a report to the Bayer Pharmacovigilance team. The primary goal was to facilitate the capture and identification of patient retinal scans that were directly attributed to treatment with a specific retinal drug, and to report such issues directly to the company pharmacovigilance team for immediate follow-up. Secondary goals included the ability to collaborate with specialists and to discuss potential issues with patients, before and after treatment, and to facilitate direct secure communication for consultation and referral of patients.

Pre-pilot Configuration and Training

The Verified team spent time with the pilot participants discussing how taxonomy and identification of images would work, creating a mutual list of identifiers and categories with which to create metadata attached to images. Part of this discussion involved how clinical terms and metadata could be used to provide accurate search criteria to identify specific ailments such as a detached retina, a retinal tear or a retinal lesion. Several fields of data that would help in diagnosis including the patient health number, date of birth and previous medical history were included.

Each user had a secure user account, grouped by clinic location and in a pilot user group. Grouping allowed for taxonomy master lists to be shared securely between accounts, to provide a common taxonomy language across accounts. Verified provided online webinar training sessions and video snippets to participants as quick reference materials.

Pilot Launch

Following initial configuration and training, the pilot launched giving participants three weeks to familiarize themselves with the system, and to start communicating via Verified Medical directly with the retinal specialist. Each participant uploaded data into Verified Medical through the web platform. Images and data were uploaded through the web platform, allowing the doctor to add notes, describe issues and select taxonomy. As part of this process, individuals could share data with the retinal specialist and with individuals within the pilot group if they so wished.

Three weeks after launch, a webinar conference call was held to gain feedback form the pilot participants and assist with questions. Initial feedback was positive, with some valuable modifications to streamline the workflow and upload process..

After initial launch, the pace increased as the participants gained confidence in the platform and Verified saw several consultations between the retinal specialist and individuals. No issues had been presented that were a direct adverse effect of the specific drug, and daily reports were created with null results, confirming with the pharmacovigilance team that all was well.

Mid-way through the pilot, a request was submitted asking for the ability to share the results of a consult or query with the pilot group, adding a learning tool and group discussion to the platform. This formed a live knowledge base and educational tool, where symptoms and management could be identified and provided to other ophthalmologists for reference in similar cases. As more data was entered into the system, this feature would have greater power and would eventually assist in the early diagnosis of ailments.

Challenges and Changes

As the pilot progressed, Verified held weekly review calls with participants and made several minor, but effective, changes to the system in direct response to participant requests. These changes included updates to data entry screens, renaming of certain fields, updating the graphical interface and increased auditing and internal messaging between users. Changes were made as hotfixes to the platform and were implemented with benefit to both pilot participants and the Verified Medical community.

Pilot Completion and Review

Verified extended by a period of 4 weeks to allow for a wider evaluation of the platform. As participants became comfortable with the platform and the workflow, more data and images were added. Each day the pharmacovigilance team received a daily report. Due to the volume of images and data that were tagged for their immediate attention, these reports would be generated daily, although the frequency could be changed to suit requirements. Where taxonomy did not indicate an adverse effect, the report would be generated with a null result, confirming that the report was running and that no results had been found that merited attention of the pharmacovigilance team.

Following the completion of the pilot, members of the Verified team visited pilot participants representatives of the pharmaceutical company for round-up meetings and discussion of whether goals were met. During this meeting, the retinal specialist navigated some of the cases that he had dealt with and showed participants how Verified Medical aided in quick diagnosis of ailments; showing cases that required further treatment, some that needed ongoing management and others that were suspected ailments that needed no treatment at all. It was deemed that some of the patients in these test cases would not have required any medical intervention and need not have visited the specialist for consultation.

It was recognized that the platform would make referral of patients easier, providing adequate medical history and case notes and accurate, high resolution imagery for faster diagnosis. The retinal specialist was able to determine if an appointment was necessary and could accept the electronic referral using visual data. For the Province of Ontario, the retinal specialist was also able to bill the provincial healthcare insurer for the costs of the consultation using standard telehealth billing codes.

Outcomes

The pharmaceutical company pharmacovigilance team required a set of sample data that could be handled electronically to provide fast identification of adverse effects as a direct result of the administration of one of their drugs. The pilot provided a secure method of uploading and communicating sensitive patient data and images, with an ability to notify the pharmacovigilance team when necessary. The primary goal of the pilot was exceeded with several value-added benefits to the retinal specialist and pilot participants. These included additional billing opportunities, faster consultation and diagnosis of ailments, an ability to share and collaborate on patient case files to assist in further education and the ability to generate rich referrals using images and case data.