

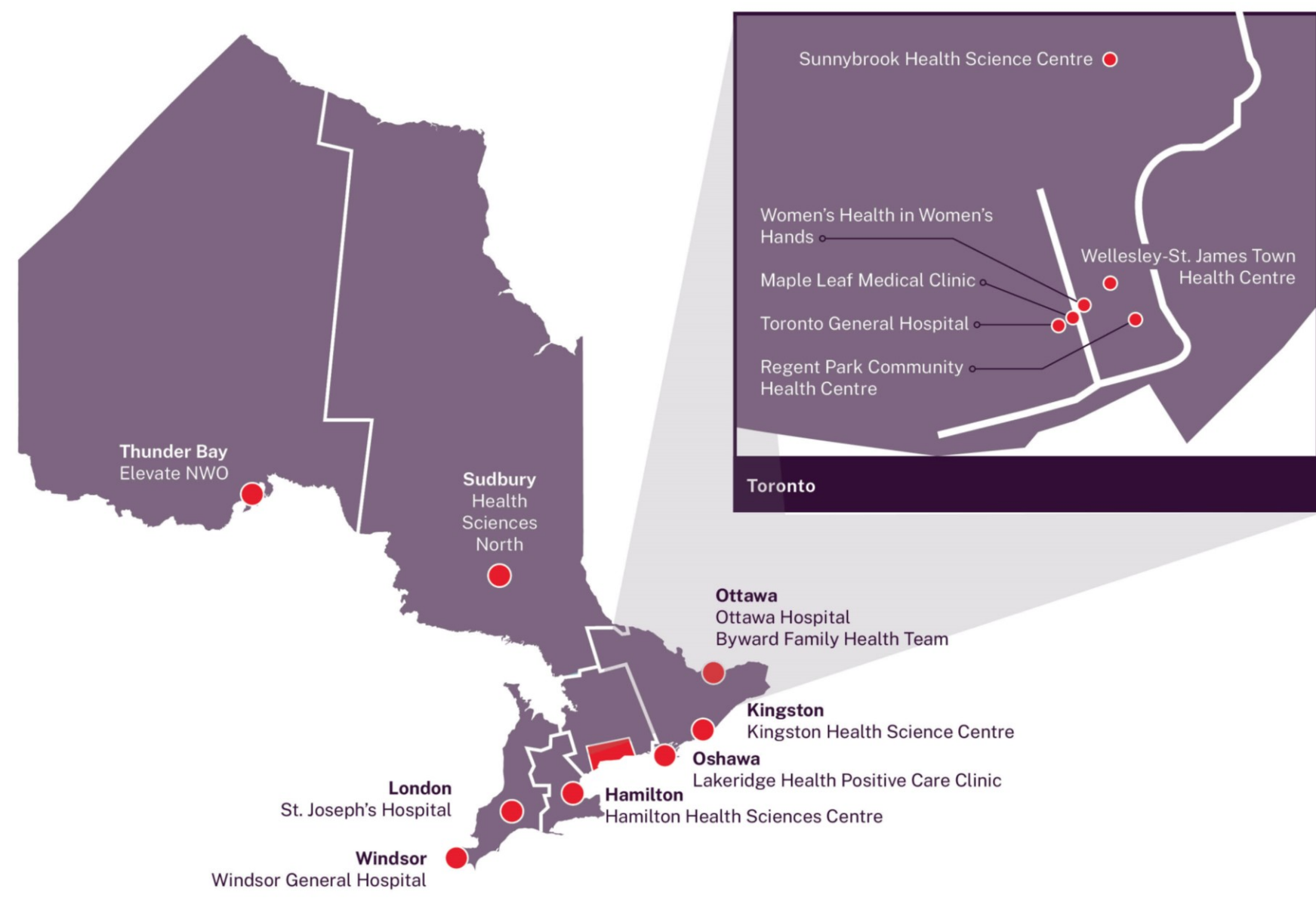
# Secure-cloud based application for cohort study maintains patient privacy and permitted continued productivity during COVID lockdowns

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## Background

Cohort studies require the collection of personal identifying information (PII) in order to manage recruitment, consent and line to health databases. The maintenance of this information is high risk for participants, and the sharing of this information can be restricted based on the varied setting of clinical data collection. The OHTN Cohort Study (OCS) has been operating in Ontario since 1995 and currently collects data from 15 clinics in Ontario. PII is restricted to the clinical site and cannot be shared across clinics or with the parent study. The OCS worked with a vendor to develop a complex security platform, which not only restricts access to personal information to the sites, but enabled the deployment of the study during COVID restrictions to continue data collection and recruitment.

Figure 1. OHTN Cohort Study sites



The OHTN Cohort Study (OCS) is an open cohort following people living with HIV at 15 clinics in Ontario, Canada.

Figure 2. OCS Data Collection

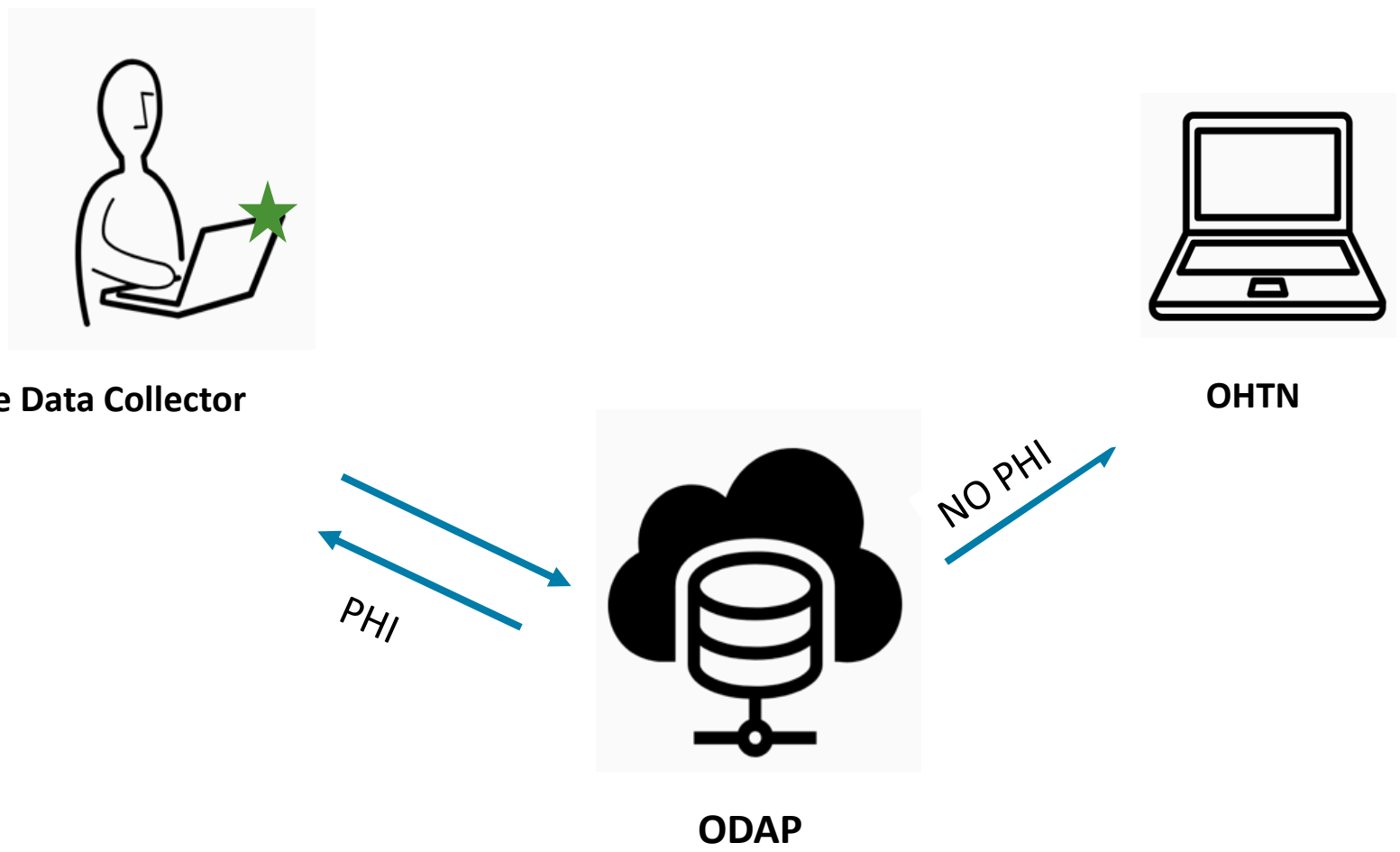


The OHTN Cohort Study (OCS) has been operating in Ontario Canada since 1995 with over 8000 enrolled and almost 6000 active participants in 2021. For context, approximately 20,000 people diagnosed with HIV were living in the province in 2020. People living with HIV over the age of 14 who are patients at OCS clinical sites are eligible to participate. At each clinical site, there are data collectors who support the study. These data collectors conduct clinical chart abstractions from both paper and electronic records. A manual chart abstraction is conducted once per participant per year. For sites with robust electronic systems, an annual abstraction takes place. Data collectors manage all consents and withdrawals from the study. Most sites are governed by their own ethics boards and follow different consent procedures and study processes. When a participant joins the study they conduct an initial baseline interview, including questions regarding HIV risk and demographics. Subsequently, participants are invited to participate in a follow up interview with a variety of questions regarding mental health, sexual behaviours, substance use, and psycho-social indicators. Every year the questionnaire is updated to ensure that it is timely and relevant to emerging issues impacting people living with HIV.

## Methods

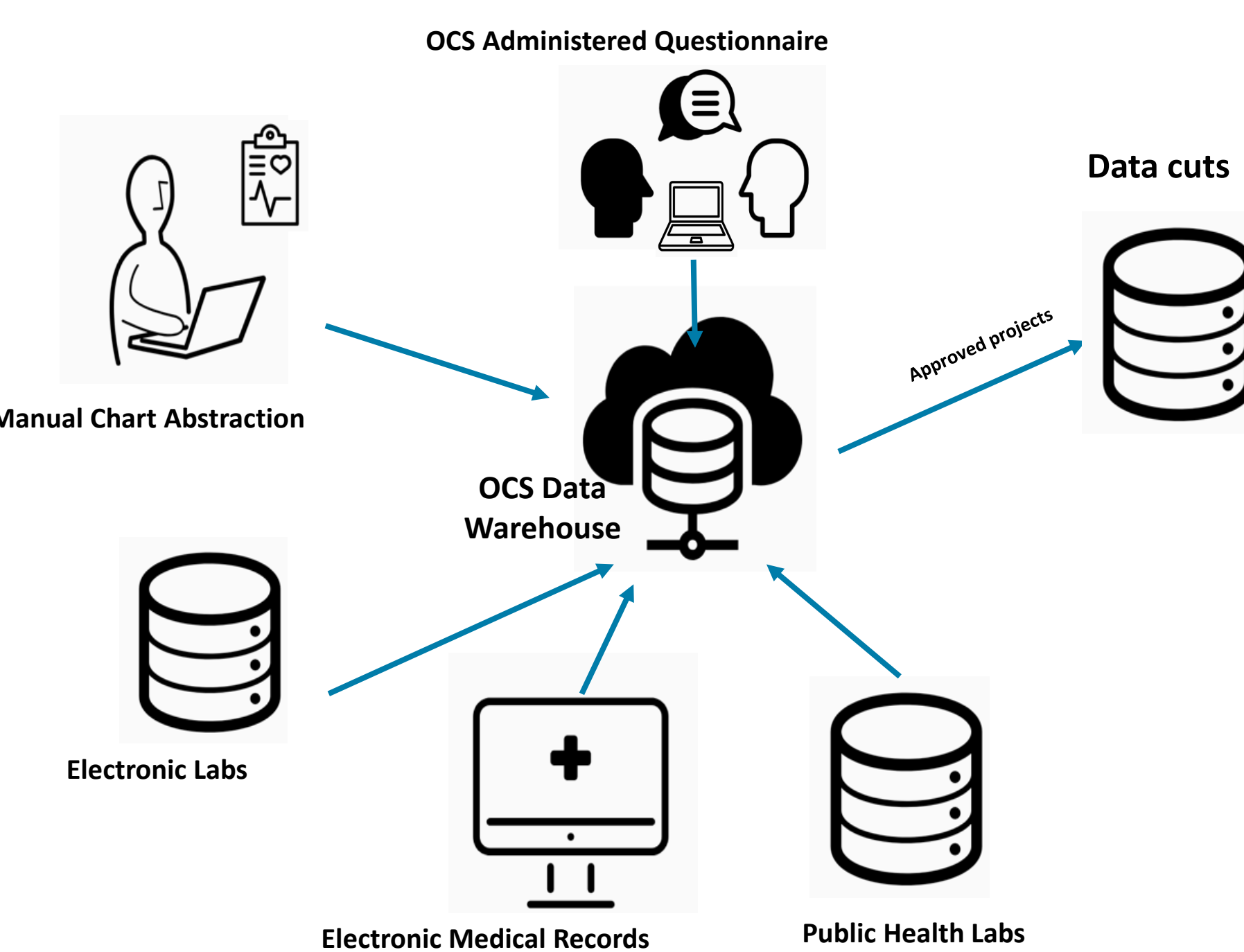
The OCS secure cloud-based application operates in MS Azure platform and is deployed through site-specific laptops. At the site level, a data collector can collect PHI and monitor who in their clinic has been approached, declined, consented or withdrawn from the study. The platform also enables the data collector to launch questionnaires and to collect data through manual chart review. Each site laptop is uniquely configured with a security certificate that is able to decrypt their participant PHI. All PHI at the parent study is encrypted and cannot be decrypted by study personnel. First name, last name, date of birth, and health card numbers are used to create unique one-way encrypted hashes that can be used to link participants and to monitor duplicate enrolment at sites. These hashes can be fed into a custom application that allows linkage with other data sources. This platform was deployed at all study sites in January of 2020.

Figure 3. Integration through the OCS Data Administration Portal (ODAP)



The OCS Data Administration Portal (ODAP) serves as the single point of contact for all activities of a data collector. ODAP is a cloud based application hosted in MS Azure, designed with state of the art security to ensure the privacy and security of participant data. The study ethics framework requires that all personal health information (PHI) be retained by the site and never transferred to the main study operated at the Ontario HIV Treatment Network (OHTN). Each site has a unique security certificate installed on their study issued laptops. This certificate allows that site to decrypt the PHI of their participants only. This includes name, health card number, and any contact information. The site only sees information about their own participants. The OHTN is able to see study information as the data collectors enter it and monitor productivity and data quality in real time.

Figure 4. OCS Data Assets and Infrastructure

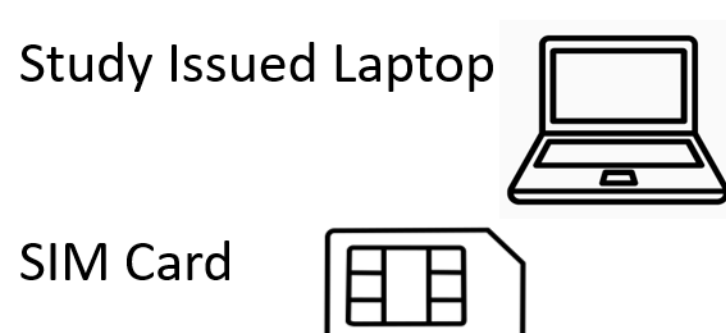


The OCS collects and aggregates data from multiple sources. In addition to supporting study activities and manual chart abstraction, ODAP also launches the questionnaire and manages links to sub-studies. The questionnaire is coded in Qualtrics. The linkage between ODAP and Qualtrics allows for variables to be piped directly, limiting manual entry of participant and site IDs. Data is also obtained from electronic labs and records at sites. To link to the public health lab, one-way encoded hashes of name, date of birth, and health card number are sent by the main study and matched to the full database of laboratory records. Participants who no longer attend an OCS clinic may still provide lab data for ongoing monitoring. All data is transferred to the OHTN and integrated into a MS Azure hosted data warehouse that is directly linked to ODAP. The data warehouse is used to produce data cuts for external researchers.

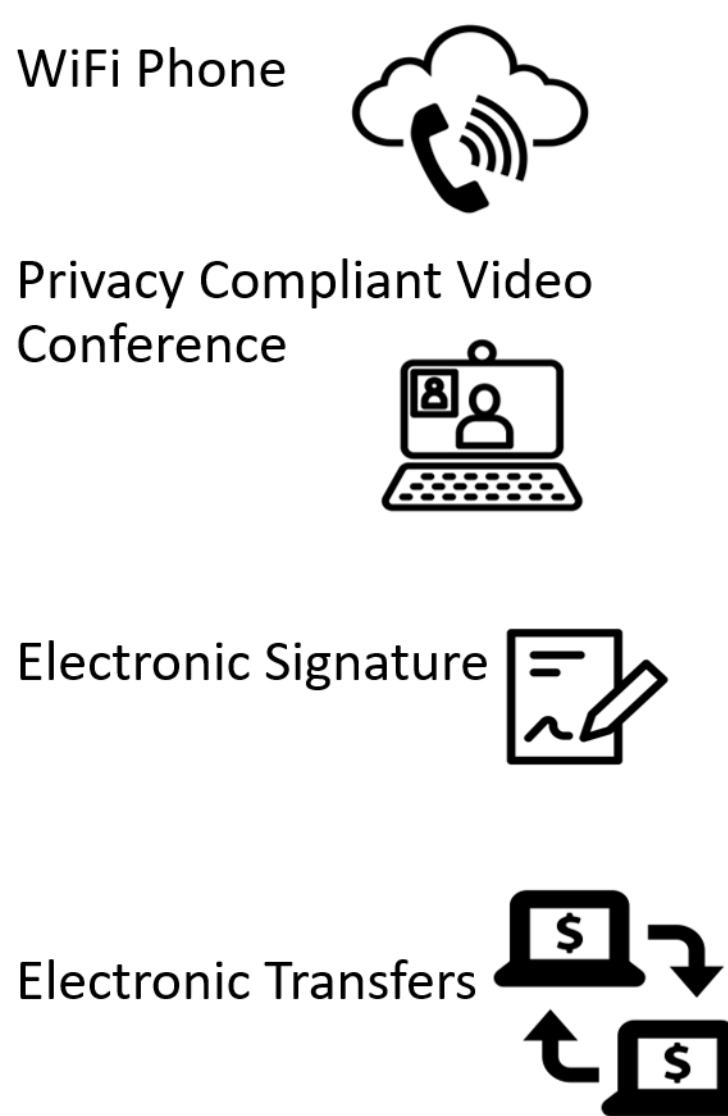
Figure 5. Hardware and Software deployments improvements for COVID

The OCS was well positioned for data collection during COVID having already implemented the ODAP platform before the pandemic. Lockdowns began in Ontario in March 2020 and restrictions have continued, imposed at varying degrees to date. Many clinical sites were closed to essential personnel only and research activities on site were suspended. Data collectors were allowed to work from their homes. In order to ensure that privacy was maintained while data collectors were off site, a number of additional software resources were made available. All data collectors were given access to a unique phone number and WiFi phone application so that they could maintain communication with participants without using personal devices in the home. Data collectors are able to conduct interviews using video conferencing and phone conversations. They are able to continue consenting participants with verbal consent or electronic signature. Honorariums are paid using electronic bank transfers, PayPal, electronic gift cards, mailed cheques, or deferred cash pickups. Each site makes payments based on the capacity and ethics guidance of their institution.

### Hardware components



### Software components



## Acknowledgements

The authors gratefully acknowledge the OHTN Cohort Study team, people living with HIV who volunteer to participate in the OHTN Cohort Study, OCS Governance Committee, Indigenous Data Governance Circle, and Scientific Steering Committee members, interviewers, data collectors, research associates and coordinators, nurses and physicians who provide support for data collection, OCS staff for data management, IT support, and study coordination. We also acknowledge Public Health Ontario, for supporting linkage with the HIV viral load database. The OHTN Cohort Study is supported by the Ontario Ministry of Health.

<http://ohtncohortstudy.ca/acknowledgements/>

## Results

The deployment of the platform permitted data collection to continue at clinics, even when clinic access was restricted. Minor adaptations were made to the platform to permit scheduling and notes, and additional software applications were deployed so that data collectors with permission could work from their homes. The study deployed unique WiFi phones that data collectors could use to communicate with participants and conduct interviews without using personal devices, as well as privacy compliant Zoom licenses. Consent procedures were carried out using verbal consent or electronic signatures, based on site ethics approvals. The deployment of honorariums were handled using a variety of means depending on the site, including PayPal, e-transfers, mailed cheques, clinic cheque/cash pickups, gift cards, or deferral. In 2020, a total of 1938 interviews were completed, compared to 2088 in 2019, a decrease of only 7% and an increase of 9% related to the 1913 completed in 2018. The number of active participants was 4330, with an additional 74 people consented from April-December 2020.

Figure 6. OCS Data Administration Portal (ODAP) Dashboard

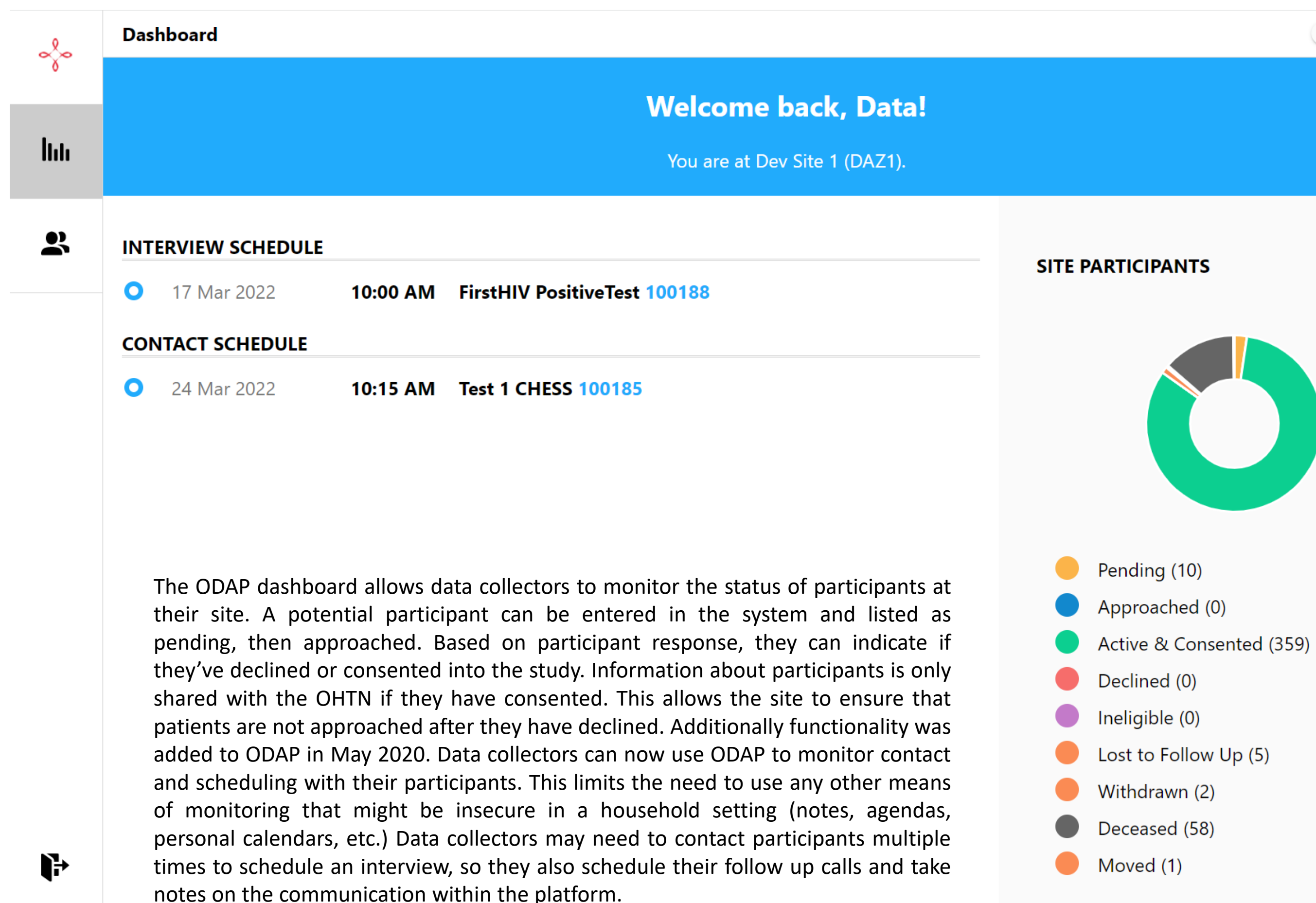
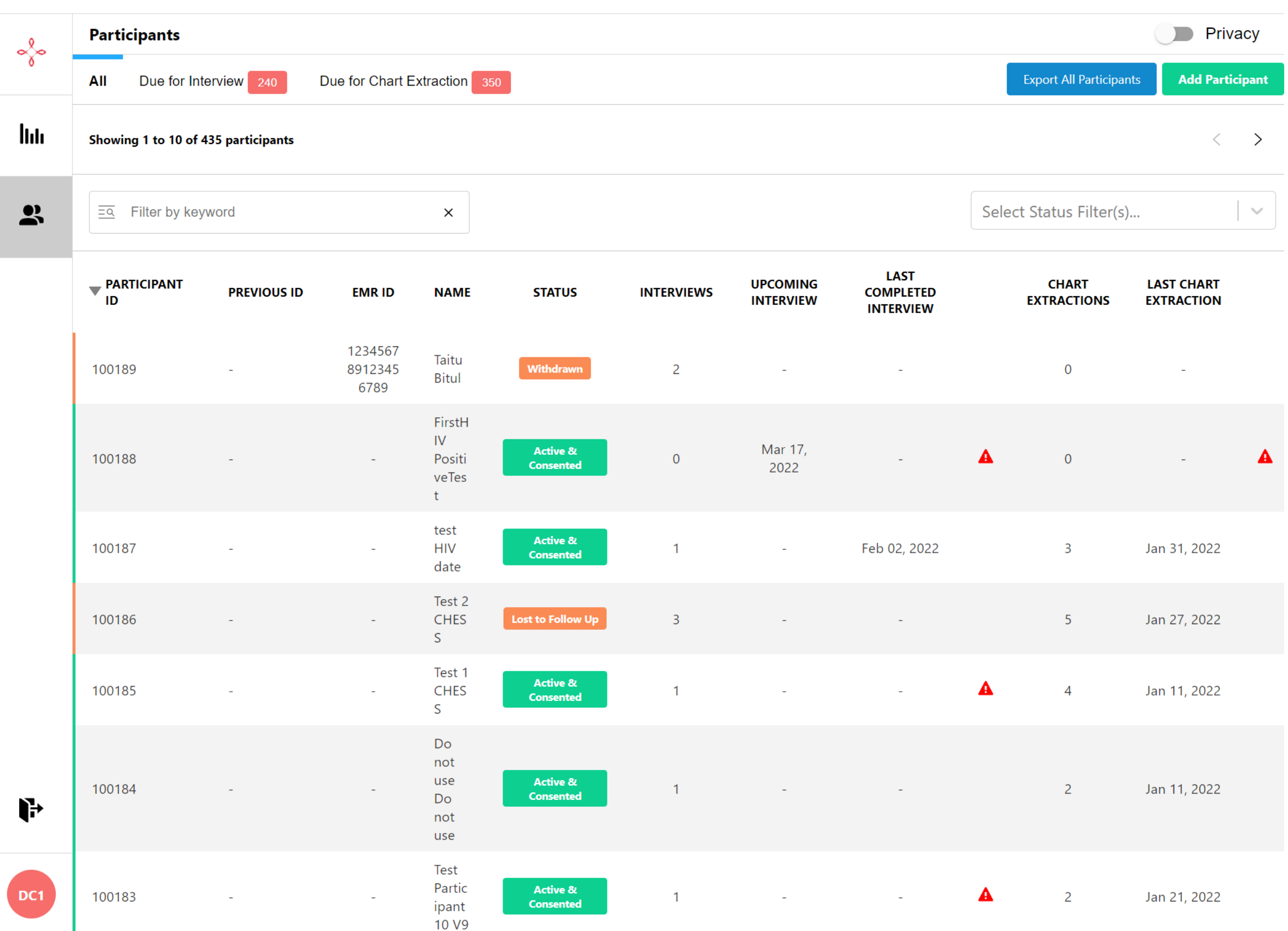
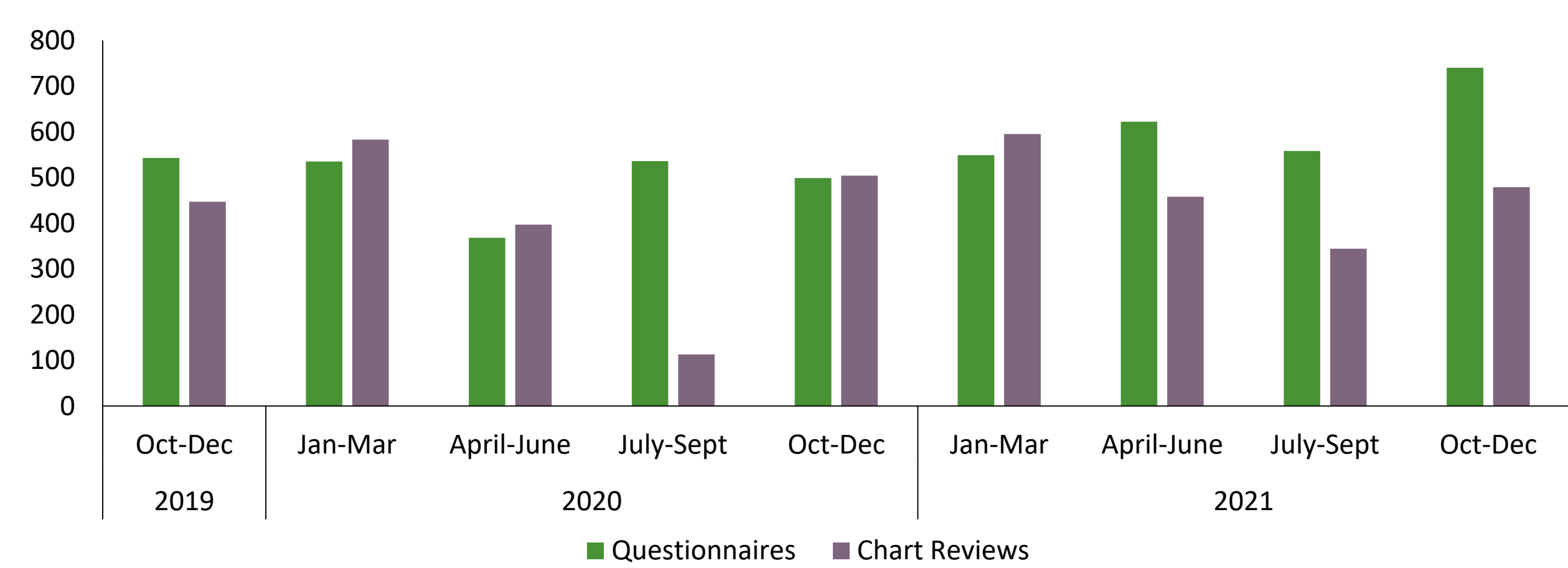


Figure 7. ODAP Participant Monitoring



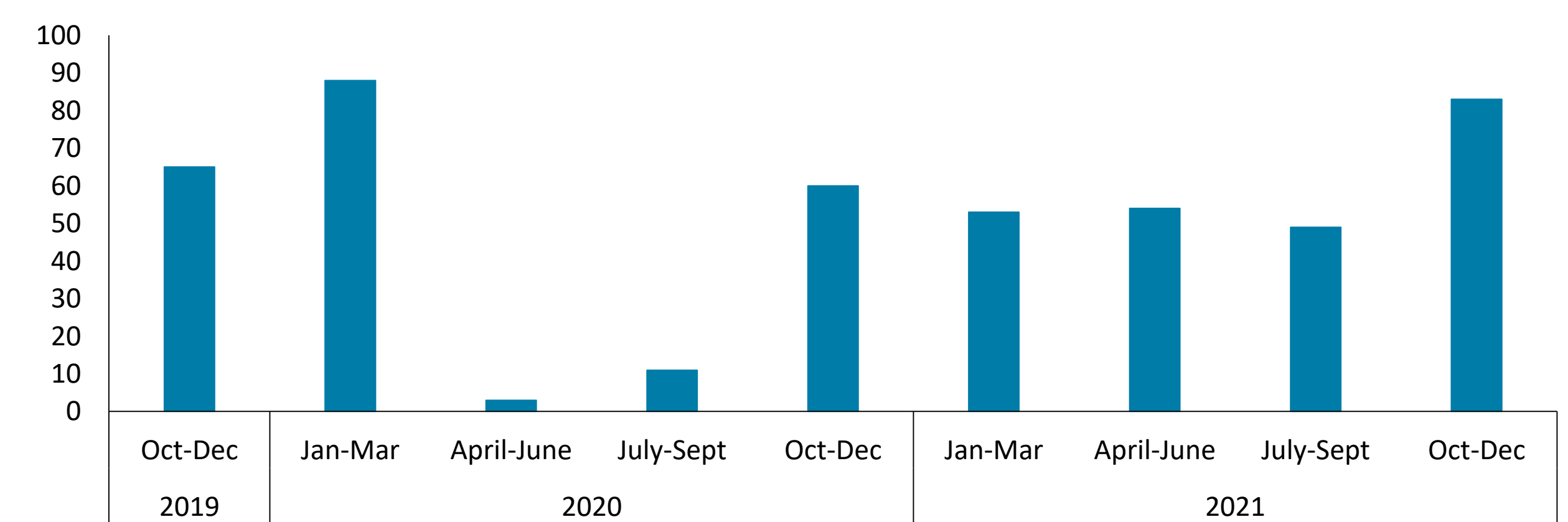
ODAP includes a summary for all patient information that includes patient status and scheduling. There is a privacy mode that hides participant names if data collectors are working in a less secure location. They are also able to see who is due for an interview or chart extraction, as well as export all participant information for linkage purposes at the site, using their clinic identifier (EMR ID), which is also encrypted and not decipherable by the parent study.

Figure 8. Questionnaire and Chart Reviews from Oct 2019 to Dec 2021



The above graph shows that April-June 2020, during the first round of lockdowns, the number of questionnaires completed declined 31%. Productivity recovered quickly and by Oct 2020, questionnaire productivity reached pre-pandemic numbers. Productivity improved through 2021 with the final quarter of 2021 approximately a third higher than pre-pandemic numbers. Chart review completion is variable based on access to clinic records and has lagged during the pandemic.

Figure 9. New Study Participants from Oct 2019 to Dec 2021



The above graph shows the number of new study participants by quarter. In the early pandemic, new consents lagged significantly, but began to recover by Oct 2020. While new consents were lower through most of 2021, by December they had reached pre-pandemic levels. As of Dec 2021, there were 4,223 unique participants active at OCS sites.

## Conclusion

The technology upgrade of the deployed platform permits a wide range of study activities, while protecting participant privacy. The encrypted cloud-based platform permitted the study to continue during lockdowns with a high degree of productivity.