

QoVAX Program: Queensland statewide digitally-integrated biobank and linked data repository to track COVID-19 vaccine and health outcomes



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Background:

The Queensland COVID-19 Vaccine Safety and Efficacy Trial (QoVAX) Program was designed to investigate multiple host and viral intrinsic and extrinsic factors influencing immune responses to COVID-19 vaccines in Queensland. Transformative physical and digital infrastructure was needed to support research to evaluate real-world community health outcomes and experiences of COVID-19 vaccines, and SARS-CoV-2 infection.

Methods:

The QoVAX Program built a digitally-integrated biobank and dynamically linked data repository that enables the management of an array of information and specimen types over time to address specific research questions involving epidemiology, genomics, virology and immunology related to COVID-19 vaccine responses.

Through partnership with 12 health service agencies, five academic institutes and private pathology services, the QoVAX Program was able to rapidly develop a research platform to underpin ethically approved research (HREC/2021/QRBW/74899, HREC/2021/QRBW/79314, HREC/2021/QRBW/81904). Individuals engaged in community (in person, by phone or online), were informed and gave consent and questionnaire data electronically via REDCap project forms. Participants could choose to give specimens at public or private pathology services, for centralized testing (primary measure SARS-CoV-2 IgG) and biobanking. Derived data from each source is integrated within the QoVAX Biorepository, embedded within Queensland Health Clinical Business Intelligence, incorporating with informed consent linked participant health data including future episodes of care, allowing for analysis of medium-term health outcomes.

Figure 1. QoVAX participant journey and flow of samples and data for research

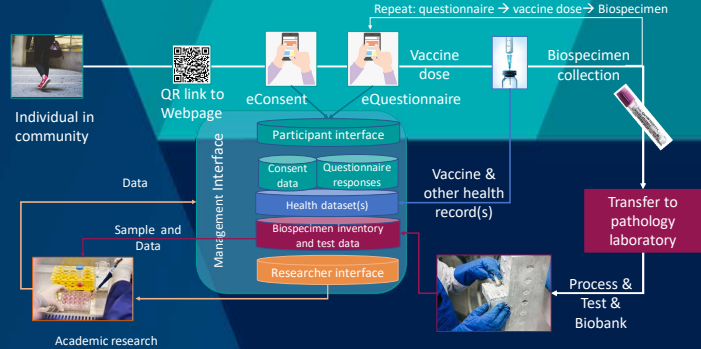


Table 1. Overall numbers of participants consented for the three QoVAX studies[#]

| QoVAX STUDY | PILOT | BOOST | MIXED DOSE 1 & 2 | STATEWIDE |
|--|------------------|------------------|-----------------------------------|--|
| Date first person recruited | 05/08/2021 | 13/12/2021 | 10/01/2022 | 25/03/2022 |
| Date last person recruited | 02/03/2022 | 18/07/2022 | 03/05/2022 | 17/10/2022 |
| Number who viewed participant information | 1,702 | 1,534 | 1,505 | 14,176 |
| Number consented | 1,093 | 1,029 | Mixed Dose: 105 Same dose: 470 | 7,393 |
| First study timepoint | T0 = pre dose 1 | B1 = post dose 2 | MD1 = post dose 2 | SW1 = any, or no, vaccine dose in last 12 months |
| Questionnaire (% of consented) | | | | |
| Complete | 1,049 (96.0%) | 933 (95.9%) | 104 (99%) | 336 (92.8%) 6,970 (94.3%) |
| Incomplete/ not done | 44 (4.0%) | 96 (4.1%) | 1 (1.0%) | 34 (7.2%) 423 (5.7%) |
| Sample given (% of consented) | 1,052 (96.2%) | 888 (85.7%) | 77 (73.3%) | 223 (47.4%) 4,969 (67.2%) |
| Second study timepoint | T1 = post dose 1 | B2 = post dose 3 | MD2 = post dose 3 | |
| Questionnaire (% of consented) | | | | |
| Complete | 739 (67.6%) | 467 (45.4%) | 29 (27.6%) | 137 (29.1%) |
| Incomplete/ not done | 354 (32.4%) | 561 (54.5%) | 76 (72.4%) | 337 (71.7%) |
| Sample given (% of consented) | 733 (67.1%) | 493 (48.0%) | 23 (21.9%) | 98 (20.9%) |
| Third study timepoint | T2 = post dose 2 | | | |
| Questionnaire (% of consented) | | | | |
| Complete | 372 (34.0%) | | | |
| Incomplete/ not done | 721 (66.0%) | | | |
| Sample given (% of consented) | 279 (25.5%) | | | |
| Withdraw (% of completed) | 28 (2.6%) | 28 (2.7%) | 0 | 14 (3.4%) 19 (0.3%) |
| Self-reported prior/current COVID-19 (at baseline) | | | | |
| Yes | 1 (0.1%) | 90 (8.7%) | 14 (13.3%) | 103 (21.9%) 3205 (43.4%) |
| No | 1001 (91.6%) | 784 (76.2%) | 90 (85.7%) | 335 (71.3%) 3880 (52.5%) |
| Missing data | 92 (8.3%) | 155 (15.1%) | 1 (1.0%) | 32 (6.8%) 308 (4.2%) |

Numbers subject to change with data cleaning and analysis

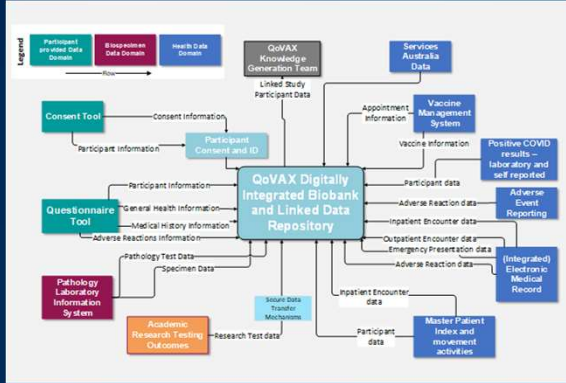


Figure 2. QoVAX Digitally-Integrated Biobank and Linked Data Repository sources for participant, biospecimen, and health data domains

Results:

During 2021, the QoVAX Program designed and implemented a digitally-integrated biobank and data repository that links with individual informed consent the triad of data sources from three overarching domains: i) participant provided survey data on general health, social determinants and vaccine experiences, ii) biospecimens and derived genome sequencing, microarray, humoral and cellular immunology data, and iii) dynamically-integrated, state-wide public hospital electronic healthcare records. This digitally enabled research platform, embedded in the public health service, was used to recruit 10,114 participants from communities covering 86% of Queensland postcodes, across three studies (ACTRN12621001543875; ACTRN12621001524886; ACTRN12622000020785; Table 1) generating over 100,000 biospecimens and 11 million data points (Figure 2). Biospecimens included cryopreserved peripheral blood mononuclear cells, serum, saliva, plasma and genomic DNA (Figure 3).

The datasets and biospecimens derived from the QoVAX studies are intended to be Findable, Accessible, Interoperable, and Re-useable for COVID-19 related research. See the Health Studies Australia National Data Assets and Datacite for study data assets. <https://researchdata.edu.au/search/#/rows=15/sort=score%20desc/class=collection/q=QOVAX/p=1/> <https://commons.datacite.org/doi.org?query=QOVAX>

Conclusions:

- With low case numbers until the state borders opened in December 2021, operating in the context of a pandemic environment, the QoVAX Program enabled through inter-sector partnership, established and applied this integrated research infrastructure for real-world COVID-19 vaccine studies.
- The QoVAX Biobank and Linked Data Repository can underpin collaborative research related to any unforeseen complications of COVID-19 vaccines, and long COVID-19 health experiences and outcomes.

Figure 3. QoVAX Biobank structure (A) and questionnaire data elements (B)

