An international observational study to determine the safety of all Covid-19 vaccines

Contents

Background:

The Covid-19 vaccinations are an untried and untested MRNA technology, which has never been used in humans. No long-term safety trials have been completed for these injections, which are being injected into large populations. Most vaccinations take a minimum of ten years to develop and pass through trials, yet the Covid-19 injections were given under emergency use authorization within months of development and then a short time later given approval for use by the US Food and Drug Administration (FDA) (2020) and the Medicines and Healthcare products Regulatory Agency (MHRA) (2020) in the UK before completing phase 3 clinical trials.

According to the FDA (2018) , phase 3 clinical trials involve 300 - 3,000 volunteers, run for 1 - 4 years in duration and aim to establish the safety and efficacy of a product before it is approved for use in the general population. Only 25 - 30% of products will make it to the next phase (Phase 4) of clinical trials. The efficacy and safety of Covid-19 vaccines has therefore, according to the FDA's definition, not been established. In addition, the number of volunteers recruited for Phase 3 trials of this product is unusually high (World Council for Health, 2022). Phase 4 clinical trials involve several thousand volunteers, last for 10 - 15 years in duration and are also designed to establish safety and efficacy (FDA 2018). Covid-19 vaccines have not yet entered this phase of trial.

In addition to the lack of long-term safety trials, there is also an absence of a control group, due to the majority of those allocated to the placebo group in the pharmaceutical trials having been offered and then accepting a Covid-19 vaccination after a short period of time into the trial (Harris, 2021).

The function of a pharmacovigilance database is to monitor adverse events and capture signals which suggest a relationship between high incidences of injuries and deaths and a pharmaceutical product (European Medicines Agency, 2022). This helps to assess the safety of new pharmaceutical products, including newly licensed vaccinations, to prevent further injury. Since the roll out of these novel vaccines, there have been an unparalleled number of adverse events and life-changing injuries reported to many pharmacovigilance databases worldwide (World Council for Health, 2022). This includes over 50,000 reported deaths related to the Covid-19 vaccine. In fact, over 50% of the total reports for all vaccines in the Vaccine Adverse Events Reporting System (VAERS) database, which was set up in 1990, are Covid-19 vaccine related reports (Open VAERS, 2022).

Rationale:

Long term studies monitoring the effects of the COVID-19 vaccines on efficacy and health are lacking. Most of the recipients of the injections are not being monitored by the pharmaceutical companies, despite being part of a clinical trial, and therefore true health outcomes are not known. A control cohort is absent and most collection of data by pharmaceutical companies does not allow scientific analysis of raw patient-level data and is therefore not transparent.

Aim:

This study proposes to observe the health outcomes of those who elect to join the database via the Control Group Cooperative Ltd website (www.controlgroup.coop from all over the world. Those who have a desire to document and monitor their own health data as individuals and also as part of a large collective, can do so.

The intention of the study is to facilitate independent, comparative analysis of the long-term health of the COVID-19 vaccine-free in direct comparison with those who have taken one or more of the Covid-19 vaccinations. This will highlight any potential risks and/or benefits associated with taking the vaccines. A large cohort of around one million participants is ideal to ensure data is reliable and consistent across socio-economically different nations.

Control Group Cooperative Ltd (CGC) will act as the custodians of the health information, allowing analysis of the anonymised data to be carried out by independent data scientists and other professionals who have been approved by the CGC and the CGC's independent Scientific Committee. CGC also aim to serve the community of participants by supporting them in their right to maintain medical choice and body autonomy.

Methodology:

This study aims to run for at least thirty years to ensure the long-term health of several generations can be observed.

The health data will be collected through participants entering information into their personal record on the CGC website - www.controlgroup.coop.)

Participants will be self-selected and will volunteer to sign up, after giving informed consent for their anonymised data to be analysed. Recruitment of participants will be facilitated by marketing the study by various means including but not limited to; word of mouth, promotional materials and content on media channels.

Participants who elect to join the study will be reminded by email once a month to log in and update any previously entered information. They will be asked to log any new health conditions and comment on their health during the previous month. All participants will be asked the same questions with slight variance depending on biological sex, Covid-19 vaccination status, etc. to allow direct comparison of answers between cohorts.

A database of anonymised participant information will be built in the near future and be accessible for analysis by scientists and researchers who are given approval mutually by a member of the Scientific Committee and a representative of the CGC who is appointed by CGC board of directors.

Participating:

Participants must be over the age of 16 years in order to create their own record, consent to being a participant and upload their health information.

Any consenting participant under the age of 16, should be added as a dependent by a parent or guardian and the consent be given on behalf of the minor. Once the child reaches the age of 16, they may transition to managing their own account themselves if they wish to continue to participate in the study.

Dependents must be people who live in the same household as the account holder.

Participants can live anywhere in the world.

Anyone can participate, regardless of vaccination status- the study requires a combination of those who are Covid-19 vaccine-free and those who have had different numbers of Covid-19 vaccinations.

Participants should be committed to keeping their information up-to-date and as accurate as possible to ensure validity of results. Anyone found to be deliberately entering false information to purposefully affect the results in any way may have their account closed.

Participants must be willing to have their anonymised health data analysed by independent scientists and researchers and all participants must complete the consent process during their sign up to demonstrate this.

Participants have the right to opt out and leave the study at any time for any reason.

Study design:

This study is an observational survey, which uses self-selected participants who have chosen to sign up and self-report. By signing up, participants are agreeing to have their anonymous health data analysed by independent researchers who have passed through CGC and Scientific Committee consideration.

Upon sign up, participants will be asked a set of questions including geographical location, height, weight, body shape and more prior to joining the study.

Participants must be responsible for taking part in the study fully, by keeping their records up to date and completing the monthly health questionnaire online.

By using an online observational design, a large cohort and vast demographic can be examined. The online observational design also aids anonymity of data as anonymised health data can easily be extracted from records and therefore have no personal details such as name or address attached to it when it is being analysed.

In order to strengthen validity of the study and its results, several steps will be implemented to capture any deaths among the participants. Firstly, participants will be encouraged to print a 'notice of death' (to be implemented) to keep with their personal properties in the event that they pass away. This will inform the family member or friend dealing with these personal properties to contact CGC and inform them, and if they can do so, to provide a death certificate.

Secondly, if the participant is a plastic ID card holder, their QR code- when scanned, will also instruct the person finding it to inform CGC of their passing (to be implemented). The instructions given on the letter and QR code page will include requesting the individual to contact CGC via email. CGC may request to see the Death Certificate so that the participant's death can be verified for data purposes. This vital information will help analysts to find any trends in deaths amongst any of the cohorts in the database and be an important data point when looking at comparisons of health and wellbeing.

Thirdly, a 'buddy system' will be introduced to encourage participants to 'buddy up' with another CGC participant and give consent for CGC to contact the buddy to check the participants' wellbeing if they have not logged in to their CGC account for 3 months. This will encourage participants to continue to fill in their monthly reports which again will strengthen the validity of the study's outcomes. Finally, if the dependent of an account holding participant dies, then that account holder can notify CGC of their dependent'' death via their profile.

Funding:

Funding for this study comes solely from donations and from study participants who choose to contribute by becoming Associate members of the CGC and subscribing to pay a subscription fee. This subscription can be stopped at any time, by the subscribing participant themselves within their online account.

CGC Associates can choose to order a printed plastic version of their participation ID card to verify their participation in the study.

Any offers of other funding will be considered by CGC in agreement with the Scientific Committee and would only be accepted on the basis of zero influence of the studies activities.

Background:

The aim is to provide independent researchers, scientists and community members with the ability to analyse the mutual health data, and CGC will do so with complete anonymity for the participants. CGC have built a robust set of policies and frameworks to protect the privacy of their users' data.

The participants health records are stored and processed separately in their own data repository, which does not hold any personal identifiers (i.e., names, addresses, date of birth, email and telephone numbers) which are required as part of the account management processes.

To protect the anonymity of this data CGC have implemented a sophisticated API which manages the integration of these disparate data repositories and also manages the encryption of key meta information which CGC utilise behind their website to provide a safe and secure data management service.

All of the data is encrypted at rest and stored in highly secure datacentres utilising third party cloud services, allowing CGC to provide an almost infinitely scalable and portable solution leveraging industry best practices for the management and protection of data. All data

transmission is carried out over the internet using secure transfer protocols with industry accepted levels of encryption.

None of CGC's participants personal information is ever stored on CGC's premises and only a small number of trusted development team have access to the passwords and security credentials required to access and manage this data.

Furthermore, CGC's policy is that all software development is done using remote workstations hosted in secure datacentres which are spun up when required and terminated when tasks have been completed, ensuring that no passwords or security credentials are left on any equipment within CGC's offices or accessible via laptops or other insecure hardware. The only personally identifiable data that the study requires is an email address which is used to verify the participant and for communication purposes. This is immediately encoded and stored in a separate repository to the participant record. Therefore, the participant record never has any personally identifiable data attributed to it directly.

Management of Data and Data Security:

Individuals are able to apply for access to the analytical warehouse of anonymised health data via CGC's application process (to be implemented), after which they will be interviewed by a CGC representative appointed by CGC's board of directors or a Scientific Committee member. The individual will then be given approval or denied access to CGC’s collection of anonymous participant data.

Any conflicts of interests must be shared with the CGC board of directors and the Scientific Committee at the time of application or as soon as it arises afterwards.

Any conflict of interest may lead to disqualification of the individual from accessing participant data. This will be looked at and decided jointly by a CGC representative appointed by CGC' board of directors and a member of the Scientific Committee.

At least one member of the Scientific Committee and a CGC representative appointed by the board of directors will mutually approve those who will be given access to the data.

Upon approval of an independent analyst, an agreement must be signed by the individual which will outline what is expected of them and their responsibility to protect the integrity of the study objective and participation in the study (to be implemented).

Individuals will be reviewed by CGC and the Scientific Committee every 6 months and access can be revoked at any time for any reasons based on ethics as defined by CGC and the Scientific Committee.

Data which is made available to analysts will always be blinded of any identifying participant information to ensure confidentiality.

CGC encourage researchers and analysts to provide as much raw data as they are able within their publications to facilitate verification and replication of the analysis and enhance transparency.

CGC will also make certain stratified and anonymised data-sets available to participants of the study, through a dashboard on the website, in order to provide transparency of results and to ensure our community have the opportunity to be involved in the analysis of their own information (to be implemented).

Data Analysis:

Individuals are able to apply for access to the analytical warehouse of anonymised health data via CGC's application process (to be implemented), after which they will be interviewed by a CGC representative appointed by CGC's board of directors or a Scientific Committee member. The individual will then be given approval or denied access to CGC's collection of anonymous participant data.

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Ethical Considerations:

New participants will be told the nature and purpose of the research clearly and in appropriately used language prior to entering the study. This information will be available via CGC's website to all new and existing participants and will be translated into multiple languages as soon as is possible.

Participants can withdraw from the study at any time, for any reason. Anonymised data already collected prior to withdrawal will be utilised in analysis.

Participants will have the option to skip or to not answer any question which they feel uncomfortable answering for any reason.

Participants are encouraged to ask questions prompted by the study and have an opportunity to do so via email or by zoom. These communication channels are also there to provide support for anyone who may unexpectedly be negatively impacted by participation in some way.

Participants will be asked to go through a clear consent process which has been checked by the Scientific Committee to ensure it is informative and straightforward.

CGC will protect the confidentiality and privacy of all participants involved in the study. Data will not be shared with anyone who is not approved by CGC directors and the Scientific Committee- and even then, all data will be anonymised.

When asking for personal information, CGC will be ethically responsible for using the information gathered for the specified purposes only- for example, email address for sign up and verification of the participant and communication purposes only.

Limited personal information such as email address and card delivery address are accessible to CGC administration staff who are directly involved with participant support and distribution of cards; however, individual health data is only visible to the participant.

Research questions will be made clear and be as objective as possible. Leading questions, which prompt an answer through word choice or an inadequate range of responses, will not be used- these procedures will be checked by the Scientific Committee.

Any modifications to the protocol by CGC which may impact the participants, including changes of objectives, will require an amendment of the study protocol and will be agreed upon by the Scientific Committee.

Any competing interests of CGC or anyone else involved in the research or analysis of the data will be fully disclosed to the public to facilitate transparency and assessment of potential bias.

Dissemination:

Results and analysis will be shared by CGC and by independent analysts who have access to data. These results may be shared in various modes and places such as, but not limited to journals, articles, on media channels and websites.

All publications are expected to protect the integrity of the study objective and participation in the study.

CGC and the Scientific Committee are not responsible for regulating where and how data analysis is shared by the independent analysts but analysts will be required to share copies of

their documentation, articles and publications that are produced as a result of utilizing the participant health data with CGC.

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