Global
Birth Defects
CONGENITAL ANOMALIES

Global Birth Defects Description and Coding (GBDDC) mobile application

Instruction Manual v2 2025

Table of Contents

Global Birth Defect Description and Coding (GBDDC) App

The GBDDC App was developed by the International Committee for Congenital Anomaly Surveillance Tools. It is a mobile health tool compatible with tablets or mobile phones. The purpose of the app is to facilitate the accurate description and coding of birth defects in low-resource settings. The app is designed for surveillance and research purposes, not clinical use.

App versions

The app is available in two versions: Basic and Surveillance. The differences are shown below:

<u>Basic Version:</u>

- Functions as a reference tool
- Assists with birth defect diagnosis and coding
- Does not allow for the recording of data
- Training tool
- Does not collect any data
- App users can access the basic version using the registration code: **XJNL**

<u>Surveillance Version:</u>

- Basic version *plus…*
- Functions as a data portal to your own database (e.g. the database of a hospital, regional or national surveillance system), via collection of data, uploading of data to a secure server, and downloading of data to your own database. There is no central database, and data is not retained on the server for long-term purposes.
- Allows recording of anonymous data. App users can collect limited data:
    - Study Identifier code (Maternal and Baby) [no personal data]
    - Date of birth
    - Age in Days (Since Birth)
    - Birth Type (live/still)
    - Term/preterm
    - Photo/video
    - ICD 10 Code (Recorded automatically)
    - Text description of anomaly
- Can upload data from phone/tablet to a secure server and then download to your specific surveillance database
- Can take secure photographs/videos
- Offline use except for uploading data
- Once uploaded, all data, including photos/videos, is automatically deleted from the device
- App users need to apply for a unique registration code via an email request to globalbirthdefects@tghn.org.

- Available also in sandbox version (see p4) for potential users to see the data recording and uploading functions before applying for ethics approval.

Languages and translations

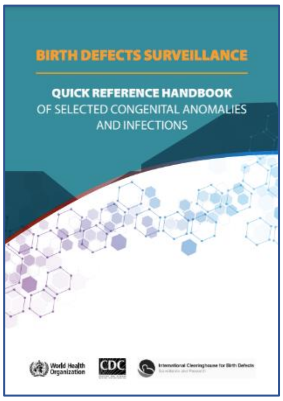
The app functions in the language that your tablet or phone is set to. The app is available in the following languages:

- English
- French
- Spanish
- Portuguese

App contents

Anomalies and syndromes:

- 120 common major external congenital anomalies
- 10 minor anomalies
- 4 internal anomalies (congenital heart defect, Oesophageal Atresia/Trachea-Oesophageal Fistula, large intestine atresia/stenosis, renal hypoplasia/agenesis with links to the relevant WHO QRH pages)
- Compatibility with the "WHO/ICBDSR/CDC Birth Defects Surveillance Quick Reference Handbook" (WHO QRH)


BIRTH DEFECTS SURVEILLANCE

QUICK REFERENCE HANDBOOK OF SELECTED CONGENITAL ANOMALIES AND INFECTIONS

For each anomaly/syndrome:

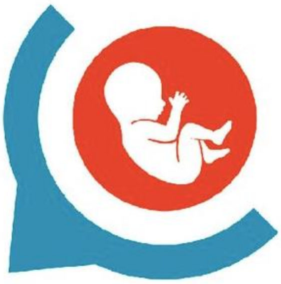
- Photos and pictures to assist with the most likely diagnosis with the ICD-10 code
- Differential diagnosis tips
- For microcephaly: instructions on how to measure head circumference, and a microcephaly calculator which designates microcephaly on the basis of sex, gestational age and head circumference

In addition, guidance in available in the "How to use the app" section of the mobile app, including neonatal examination videos, guidance on taking photographs, guidance on talking to parents, how to record and upload data (for users of the surveillance version), and good practice for consent and data protection procedures for photos and videos.

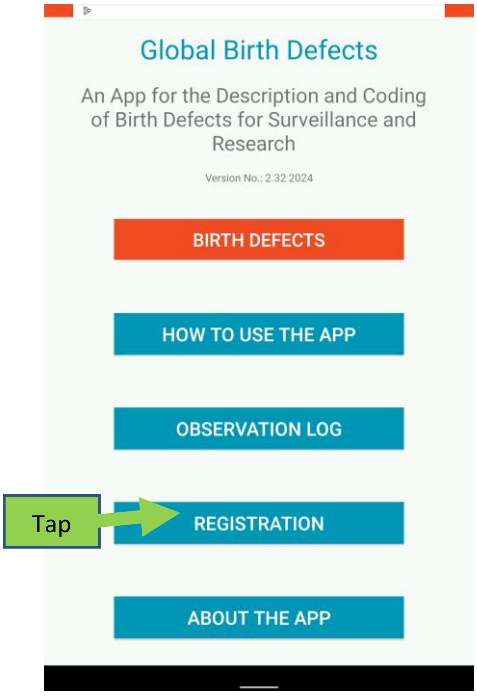
How to download the GBDDC app and register

On either Google Play or the iOS App Store, search for “GBDDC”.

The app icon looks like this:



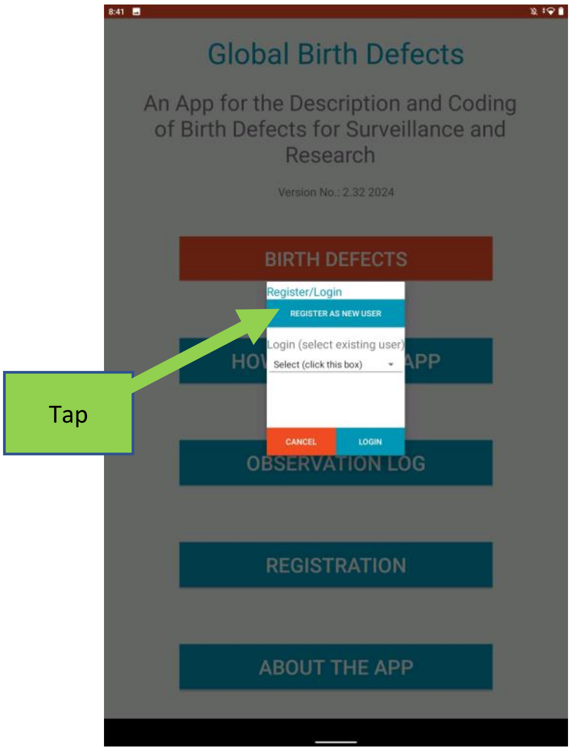
Once the app is installed and has been opened, follow the prompts to register:



Global Birth Defects

An App for the Description and Coding of Birth Defects for Surveillance and Research

Version No.: 2.32 2024



Global Birth Defects

An App for the Description and Coding of Birth Defects for Surveillance and Research

Version No.: 2.32 2024

Register/Login

Login (select existing user)

Select (click this box)

Guidance for the surveillance version

Surveillance version terminologies

- **Institution:**
  An Institution refers to any organisation, institution or project that uses the GBDDC mobile application for birth defect surveillance, research, or training of health professionals. This may include hospitals, research centres, universities, public health agencies, or non-governmental organisations.
  Within the app, the role of an institution includes:
  - Serves as the primary organisational unit under which users and data are grouped.
  - Each institution will be assigned a unique "institution code".

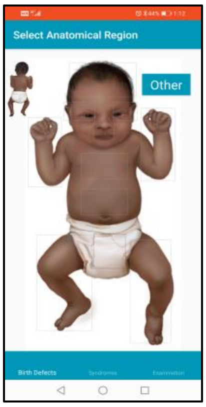
- **Institutional admin:**
  An Institutional Admin refers to designated user(s) who have the highest level of privileges to manage the backend users and data within their institution.
  The responsibilities of institutional admins include:
  - Create and manage users within the institution.
  - Assign roles and permissions to users.

What to think about before you decide to use the surveillance version

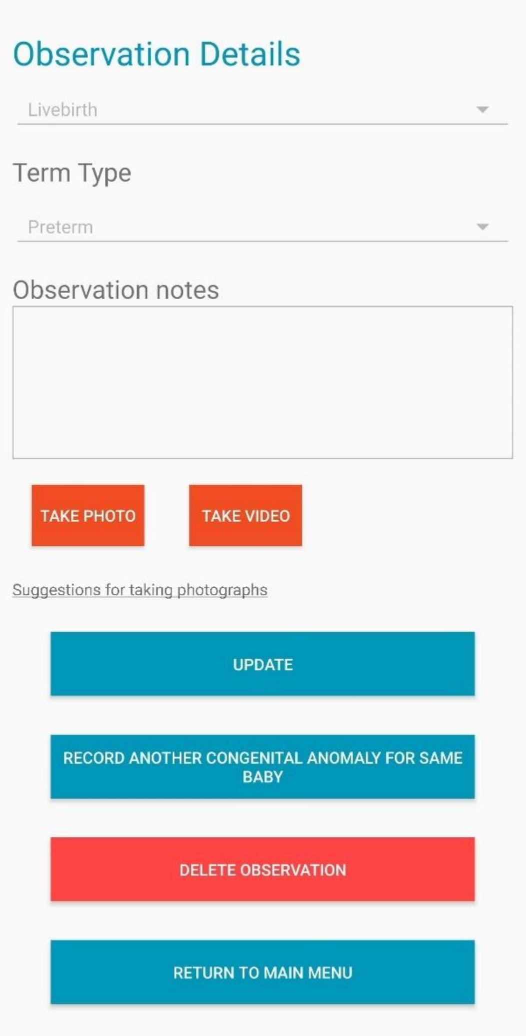
- Do you have a database?
- Do you have one database or multiple centres with their own databases?
- What is the design of your system?
- Do you have ethics permission?
- What data do you need to collect, and how will you collect it?
- Do you need additional data?

How to record data

- You will need a surveillance version of the app to record data
- On the app landing page, a picture of a baby will be displayed showing different body parts.
    - Tap on the body part where you observed the anomaly to see more pictures of congenital anomalies associated with that body part
    - Select the image that resembles the anomaly you observed
    - Details of the congenital anomaly will be displayed on the screen, including the name and ICD code.



- Once you have identified the condition and ICD Code (by completing the above steps), scroll to the bottom of the screen and press the “record birth defect” button.
- Complete the observation details and press “register this observation”.
    - Kindly note that it is mandatory to enter a reference code for the baby. This should not include any personal identifiers. You can also scan barcodes where this is available.
- You will get a pop-up prompt notifying you of the successful submission of your observation.
- This will then open options for you to take a photo or video of the condition. To take a photo or video, press the “take a photo” or “take a video” button.
    - This will prompt a pop-up confirmation that you have obtained informed consent to take photos or videos. Kindly note that you cannot upload photos or videos without confirming informed consent.
    - After taking the photo or video, select “ok” to return to your data form. On your data form, you will see your picture/video displayed with your observations. Press “update” to resubmit your observations with the picture/video.
- To record more anomalies on the same baby, press the “record another congenital anomaly for same baby” button.



Observation Details

Livebirth

Term Type

Preterm

Observation notes

TAKE PHOTO
TAKE VIDEO
Suggestions for taking photographs
UPDATE
RECORD ANOTHER CONGENITAL ANOMALY FOR SAME BABY
DELETE OBSERVATION
RETURN TO MAIN MENU

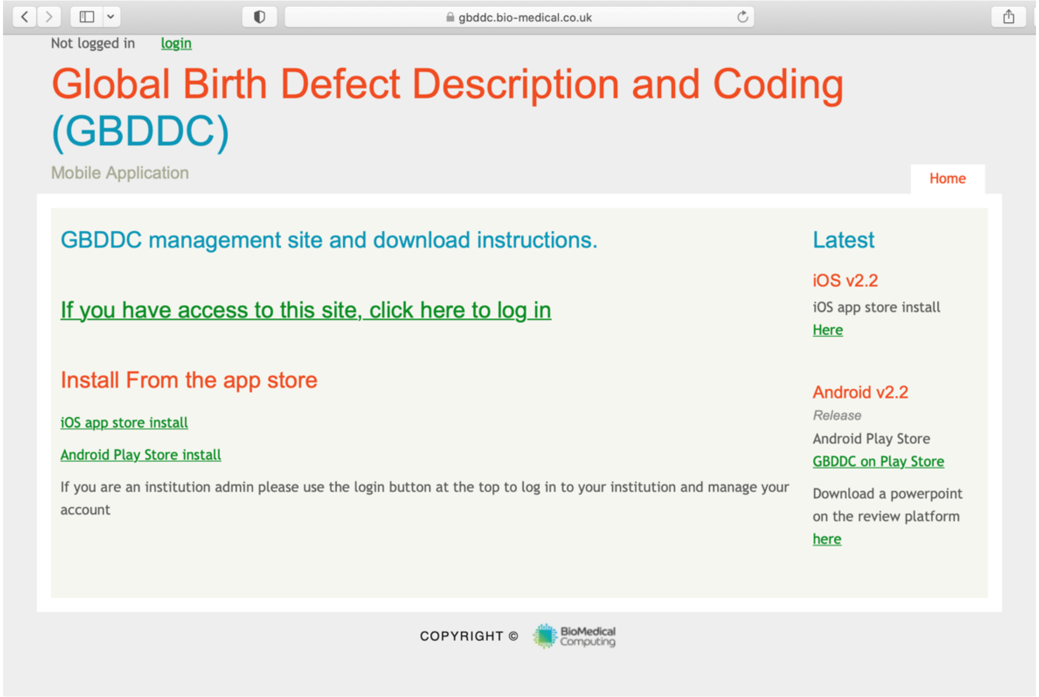
- To return to the landing page, press “return to main menu”.

Important to remember:

- Cases can be documented offline. These will be uploaded by the app once the mobile device comes online.
- Once a case is uploaded, all details and photos/videos are deleted from the device and can no longer be edited

How to download data from the server

Only the institution admin will be able to grant a user permission to access the institution’s site/data on https://gbddc.bio-medical.co.uk.



Global Birth Defect Description and Coding (GBDDC)

Mobile Application

GBDDC management site and download instructions.

If you have access to this site, click here to log in

Install From the app store

iOS app store install

Android Play Store install

If you are an institution admin please use the login button at the top to log in to your institution and manage your account

Latest

iOS v2.2

iOS app store install

Here

Android v2.2

Release

Android Play Store

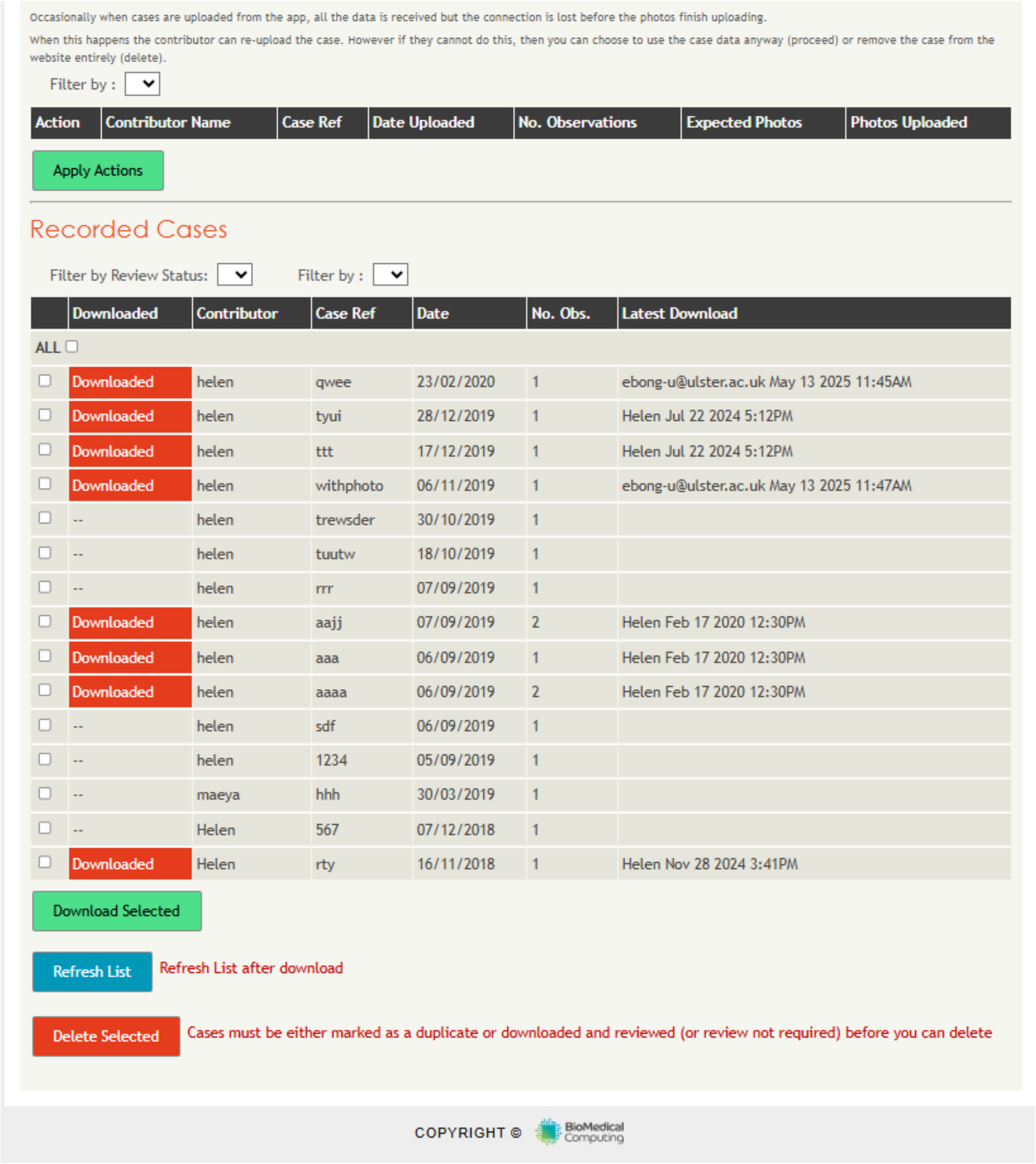
GBDDC on Play Store

Download a powerpoint on the review platform

here

COPYRIGHT © BioMedical Computing

Once you are logged in, click on the “Institution” tab to view cases uploaded by users in your institution. Select the cases you wish to download by ticking the white boxes on the left side of the screen. To select all uploaded data, click on the “ALL” tick box. Then click on the “Download Selected” button to download the data.



Occasionally when cases are uploaded from the app, all the data is received but the connection is lost before the photos finish uploading.

When this happens the contributor can re-upload the case. However if they cannot do this, then you can choose to use the case data anyway (proceed) or remove the case from the website entirely (delete).

Filter by :

Action	Contributor Name	Case Ref	Date Uploaded	No. Observations	Expected Photos	Photos Uploaded

Recorded Cases

Filter by Review Status: Filter by :

	Downloaded	Contributor	Case Ref	Date	No. Obs.	Latest Download
ALL ☐						
☐	Downloaded	helen	qwee	23/02/2020	1	ebong-u@ulster.ac.uk May 13 2025 11:45AM
☐	Downloaded	helen	tyui	28/12/2019	1	Helen Jul 22 2024 5:12PM
☐	Downloaded	helen	ttt	17/12/2019	1	Helen Jul 22 2024 5:12PM
☐	Downloaded	helen	withphoto	06/11/2019	1	ebong-u@ulster.ac.uk May 13 2025 11:47AM
☐	--	helen	trewsder	30/10/2019	1	
☐	--	helen	tuutw	18/10/2019	1	
☐	--	helen	rrr	07/09/2019	1	
☐	Downloaded	helen	aajj	07/09/2019	2	Helen Feb 17 2020 12:30PM
☐	Downloaded	helen	aaa	06/09/2019	1	Helen Feb 17 2020 12:30PM
☐	Downloaded	helen	aaaa	06/09/2019	2	Helen Feb 17 2020 12:30PM
☐	--	helen	sdf	06/09/2019	1	
☐	--	helen	1234	05/09/2019	1	
☐	--	maeya	hhh	30/03/2019	1	
☐	--	Helen	567	07/12/2018	1	
☐	Downloaded	Helen	rty	16/11/2018	1	Helen Nov 28 2024 3:41PM

Refresh List after download

Cases must be either marked as a duplicate or downloaded and reviewed (or review not required) before you can delete

GBDDC App Sandbox version

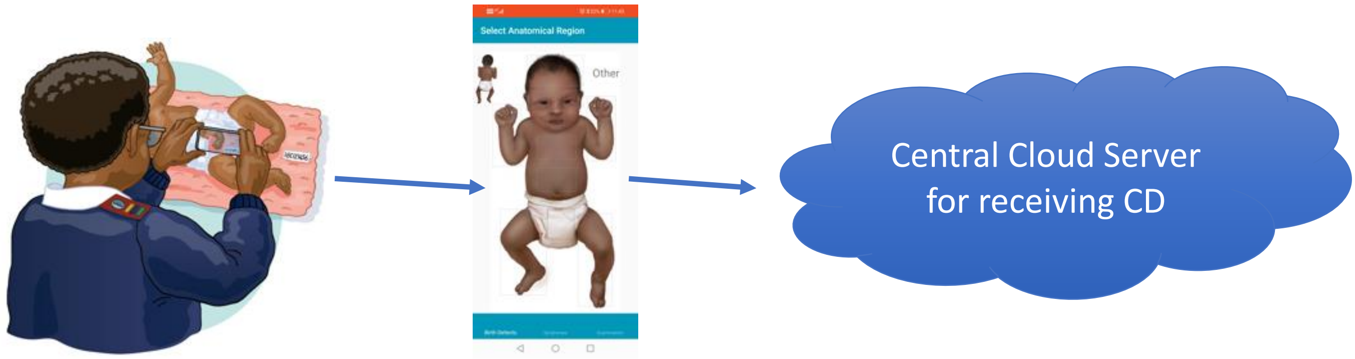
The GBDDC sandbox version is designed to enable new surveillance users to familiarise themselves with the app's features before developing their full study protocols and obtaining ethics approval for data collection. The sandbox version mirrors the surveillance version, but the registration code issued to a sandbox version user will only allow the user to upload data to the online portal for a limited time period, and photos/videos taken will be unusable. The sandbox version has all the features of the surveillance version, but when the data is uploaded to the online portal (the secure server where the data resides temporarily), the photos and videos will be watermarked as “not for use” or “sandbox”, and the videos will be truncated at 5 seconds. Please do not take photos/videos of babies or patients, but, for example, of the researchers themselves, in order to observe the process and quality. To obtain the sandbox version, contact globalbirthdefects@tghn.org. You will be sent a unique registration code (8 characters) with which to register.

Data should be downloaded to the user institution’s database (on their own server) as soon as possible after uploading. In order to test the data downloading function (from the online portal), you will have been sent a temporary passcode (20 random characters) from system@bio-medical.co.uk. When you enter the temporary passcode (which is only valid for 10 days), you will be prompted to create your own passcode. Note that the passcode is not the registration code. Instructions regarding downloading data are in the Instruction Manual (see pg7). When the data (including photos and videos) is downloaded in an Excel file to the user institution’s own database, the photos and videos will continue to be watermarked/truncated.

After the user institution has ethics approval and its application for the full surveillance version has been approved, it will receive a new registration code, which will allow full use. Photos and videos will no longer be watermarked or shortened. However, users should follow the recommendations regarding making photos and videos as minimally personally identifiable as possible.

Please test the sandbox version in a timely manner. If you need an extension, please contact the administrator. At the end of the period of sandbox use, any data still remaining on the server will be automatically deleted.

Data security (surveillance version)



There are a number of levels of data protection and security:
At the level of data collection:

- The user registers to use the app, using the unique registration code of their institution
- The user creates and uses a pin code. After 10 minutes of non-use, the device will need re-entry of the pin code
- After each case is entered, or at the end of the day or shift, the data can be uploaded to the server and will be automatically deleted from the device itself.

At the level of the data server:

- The unique registration code gives each institution or surveillance programme a distinct area of the secure server that only they have access to.
- Once the specific case gets uploaded, it is automatically removed from the device. It will now sit safely in the central cloud server. No one has access to this server. Only the allocated institution admin will be able to download cases when needed. It is secured on a server with a professional hosting company that offers all the standard security measures. The hosting company will only have limited access, and this is limited to the IP of the Biomedical Computing office.

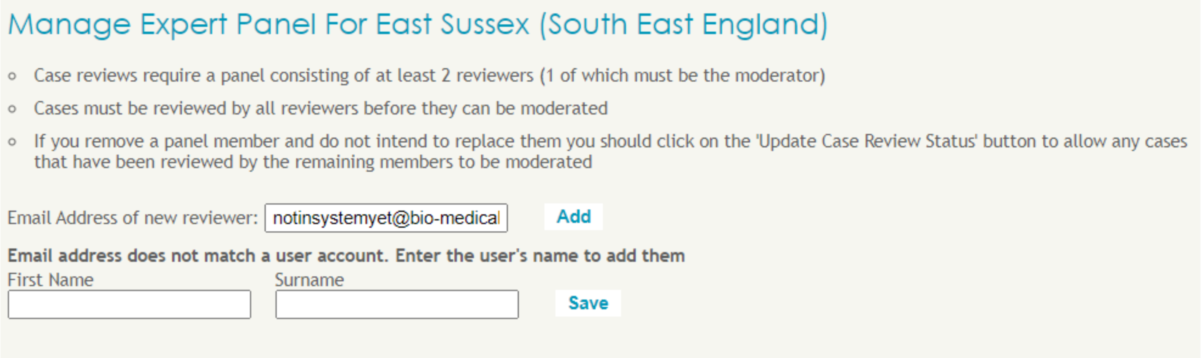
The app developer is Ulster University. The software developer is Biomedical Computing Ltd, which also provides the data hosting service. Biomedical Computing Ltd operate according to a GDPR compliant data protection policy and information security policy. See Appendix A regarding data hosting security.

The server is in the UK. Although most governments prefer data to be kept within the country, the server only functions as a route to your own in-country database. There is no central database, and the data can be downloaded from the server to your in-country database as frequently as you wish.

Triage and Review Platform

Recent updates to the app now allow institutions to set up a review panel. Review panels can only be set up by the Institutional Admin and require a minimum of two reviewers. Reviewers are invited to the panel using their email address. Please ensure you have permission/agreement first before setting up the review panel.

If they exist in the system, they will be added automatically. Otherwise, their email and name will be required, and they will be invited to join.



Manage Expert Panel For East Sussex (South East England)

- Case reviews require a panel consisting of at least 2 reviewers (1 of which must be the moderator)
- Cases must be reviewed by all reviewers before they can be moderated
- If you remove a panel member and do not intend to replace them you should click on the 'Update Case Review Status' button to allow any cases that have been reviewed by the remaining members to be moderated

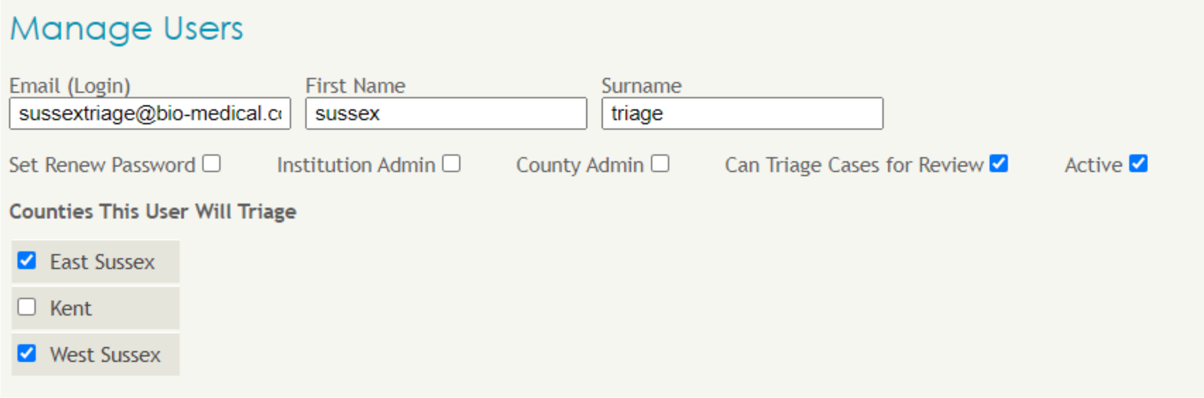
Email Address of new reviewer: notinsystemyet@bio-medical

Email address does not match a user account. Enter the user's name to add them

First Name

Surname

To add existing users as reviewers, the Institutional Admin can change their role/privileges to include triage/reviews as shown below.



Manage Users

Email (Login)	First Name	Surname
sussextriage@bio-medical.c	sussex	triage

Set Renew Password □ Institution Admin □ County Admin □ Can Triage Cases for Review ☑ Active ☑

Counties This User Will Triage

☑ East Sussex
□ Kent
☑ West Sussex

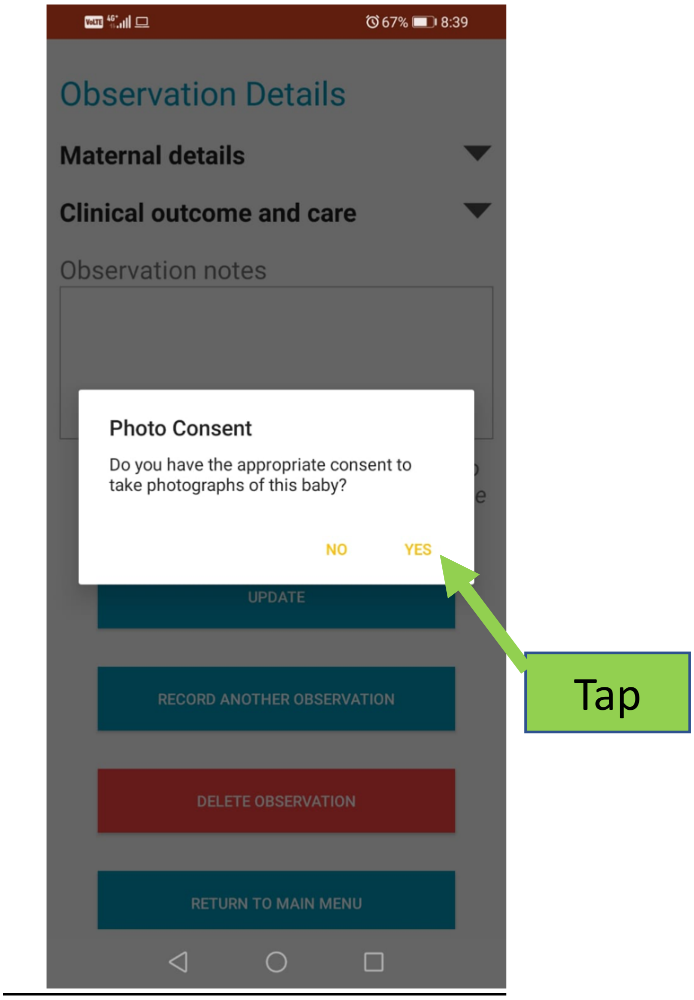
More information on the triage/review functionality can be found here.

Informed consent for surveillance version

Your institutional review board or ethics committee may require consent to be taken for each case registered, or only if a photo is taken.

Registering a case observation allows the user to take a photo or video. This is very helpful but needs consent from the parent. The app will prompt the user with a pop-up to ensure they have given consent before they can continue. The consent form itself is not asked for in order to preserve confidentiality in the data collection process. Each institution/surveillance programme must have its own procedures for collecting and storing written consent forms.

Below are images of the process.



Observation Details

Photo Consent

Do you have the appropriate consent to take photographs of this baby?

Tap

The consent form will be specific for each institution and will need ethics approval from the relevant department. All consent forms should contain pertinent information, as listed below:

- All study details: name, site leaders, address, and telephone numbers
- Information about the study purpose, why photos/videos are being taken, and benefits or risks involved
- It must state clearly that withholding consent will have no impact on your baby’s clinical care and management
- Clear signatures with names and date for the parent, staff taking consent and possibly witness
- Additionally, Permission for staff to contact the parent later might also be included
- Important for a copy of the consent to be kept securely in a folder

Appendix A: Extracts from Biomedical Computing Ltd Hosting Security and Information Security policies.

BioMedical Computing Ltd Hosting Security

Data Centre Accreditations

- ISO 9001:2015 (Quality Control)
- ISO 14001:2015
- ISO 22301:2019
- ISO 27001:2013 (Information Security Management)
- PCI Data Security Standard
- Cyber Essentials
- Cyber Essentials Plus

Physical Security

- Data centre access limited to data centre technicians
- Proximity cards for controlled data centre access
- CCTV monitoring at all data centre locations
- 24x7 onsite staff provides additional protection against unauthorized entry
- 2.8m secure perimeter fencing
- Unmarked facilities to help maintain low profile
- Independent NSOI accredited security patrols

System Security

- System installation using hardened, patched OS
- System patching providing ongoing protection from exploits
- Dedicated hardware firewall and VPN services to block unauthorized system access (direct access only available at BioMedical)
- Data protection with nightly managed backups
- Optional offsite backups available
- Distributed Denial of Service (DDoS) mitigation services
- Risk assessment and security consultation by professional services teams

Appendix B: Extracts from Biomedical Computing Ltd Information Security Policy.

The policy brings together the legal requirements, standards and best practices that apply to the handling of information.

It is the responsibility of the client to ensure that any relevant permissions are obtained before BioMedical Computing stores or processes data on their behalf. BioMedical Computing will accept responsibility for collecting, storing, or processing data as appropriate, but the client retains responsibility for any authorisations, justifications or accreditations required.

It is the responsibility of the hosting company to ensure the physical and network-level security of the web server.

Data Collection

a. BioMedical Computing can be required to store data on behalf of clients and may contain commercially sensitive information, legal documentation, confidential and/or personal data.
b. Data should only be used for the purpose for which it was collected and for the client for whom it was collected.

All data stored on the web server is to be backed up daily as per the Service Level Agreement with the hosting company. Backups are to be retained for two weeks, then overwritten. The server administrator is responsible for ensuring that these backups are carried out.

Data Access

a. All ports on the web server are to be blocked via a hardware firewall, with the exception of the standard ports required for HTTP, HTTPS and FTP access unless one of the following exceptions applies:
    i. The traffic is handled by a database server (SQL or MySQL ports), and traffic is restricted to a fixed and verified company or client IP address.
    ii. Full port access to be permitted from the offices of BioMedical Computing on a permanent basis.
    iii. Full port access may be set up from another IP address as required by a BioMedical Computing employee. In this case, the firewall rule must be created when needed and removed as soon as access is no longer needed.
    iv. Employees of the hosting company may have access to the server, including data centre technicians and support staff, as per the agreement with the company. Permission to log in to the server should be sought from a

BioMedical Computing employee. Under no circumstances should logins be provided to the hosting company that will allow viewing of client data.

b. Data stored in a database on any of the company's servers should be password protected. Each database should have an individual password such that access to one database does not give the user access to any other data.