Victorian combined ART adverse incident reporting form

User Guide

Contents

Overview

The combined Victorian Assisted Reproductive Treatment (ART) Adverse Incident Reporting Form is an on-line web portal for all registered ART providers to notify the Victorian Assisted Reproductive Treatment Authority (VARTA) and the Reproductive Technology Accreditation Committee (RTAC) of adverse incidents, as required under VARTA's Conditions for Registration and RTAC's Code of Practice for assisted reproductive technology units. Reports submitted via the portal are also automatically provided to the RTAC Auditor – either DNV or Global Mark.

Purpose

Adverse Incident Reports have previously been sent to RTAC and VARTA via email. The portal is designed to provide a single joint reporting form to notify both RTAC and VARTA of reportable adverse incidents at the same time. The system is intended to reduce administration and workloads, improve the security of transmitting notifications, and to streamline the overall adverse incident reporting process.

Notification Requirements

Information about adverse incident reporting requirements is available in the *Guidance Note - Adverse Incident Reporting.*

Generally, notification of incidents must occur:

1. as soon as practicable but no later than six (6) weeks after the provider becomes aware of the incident
2. within two (2) weeks for a potential breach of the legislation
3. within 48 hours for a sentinel event

When reporting incidents, please provide as much detail as possible. The attachment of data such as a RiskMan report is encouraged. VARTA and /or RTAC may request further information or updates later.

Roles and Responsibilities

The Adverse Incident Reporting portal has three types of user roles: Administrator, Organisation and Clinic. The table below describes each of these roles and what they can see and do in the system.

System Role	Who	Permissions
Administrator	VARTA only	Full system access; can see all reports submitted by all ART providers
Organisation	RTAC only	Read only access; can view / export submissions from all ART providers
Clinic	ART Providers	Create / view access; can create / view / export reports for individual ART provider; cannot view

submissions from other ART providers

Each clinic has a designated person to access the portal using a unique user ID. Only this person can complete and submit reports or view and export a list of reports for their clinic. The permissions do not allow users to edit or modify reports that have been submitted. Submissions can only be modified or re-submitted by placing a request to VARTA. See Modifying details after submitting the form for further details.

It is the responsibility of the designated person to submit adverse incident reports via the portal by the required notification date.

Getting Started

Obtaining an account

To access the Adverse Incident Reporting Form, you must send a request to regulation@varta.org.au.

You will be sent a username and temporary password within one working day of submitting your request.

Accessing the form

The Adverse Incident Reporting Form is available from the following site:

https://www.varta.org.au/user/login

The form is also available on the 'For fertility treatment providers' page of the VARTA website by clicking on the 'Access clinic portal' link at the bottom of the page.

https://www.varta.org.au/regulation/clinic-information

Logging in

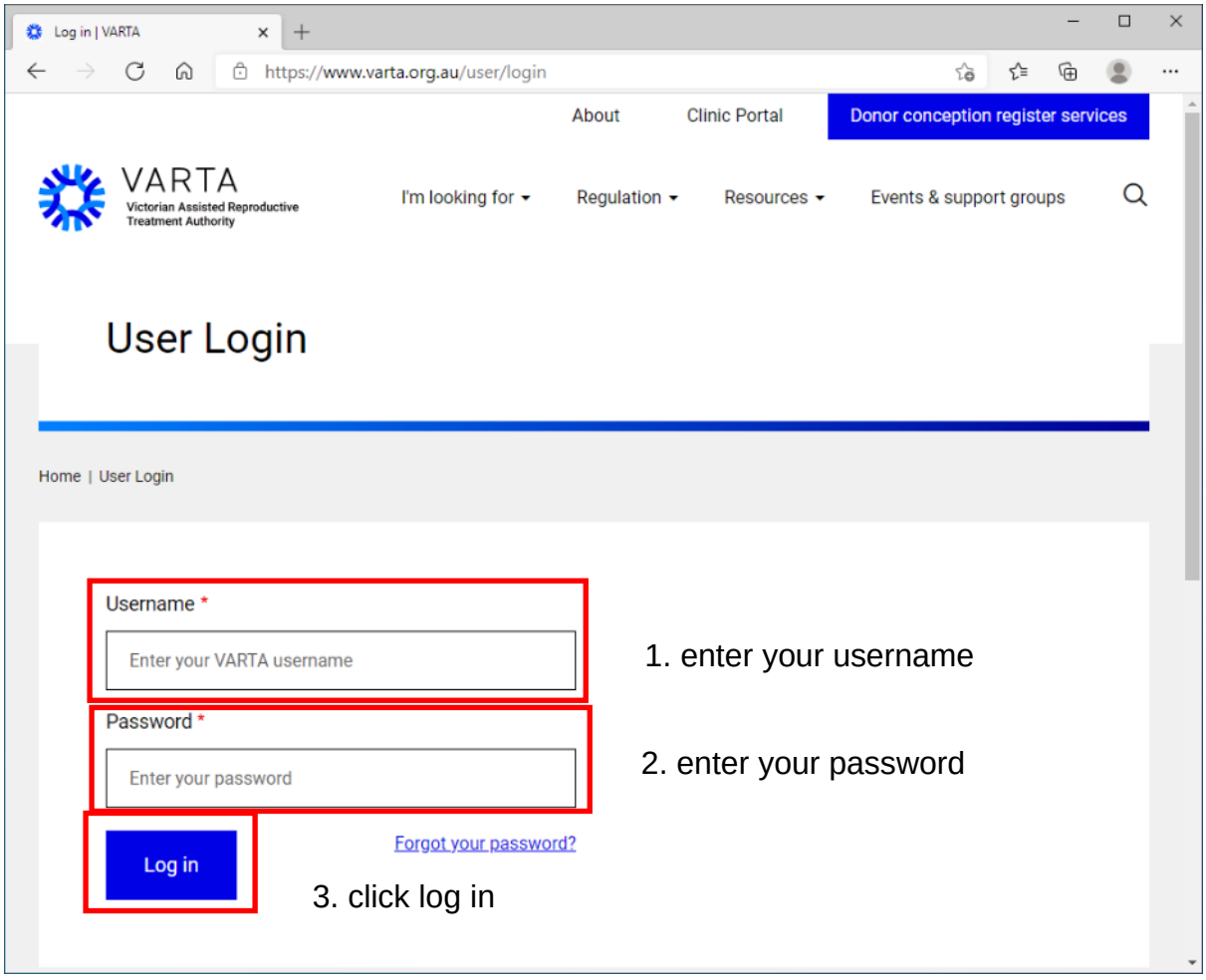
The Adverse Incident Reporting Form uses two-factor authentication to secure access to the system. Each time you log in, you will be asked to enter:

- a username and password; and
- a six-digit security code sent to your email address

You will have 5 minutes from the time you receive the email to enter the security code into the login screen.

To log in to the Adverse Incident Reporting Form:

1. Enter your username in the **Username** field
2. Enter your password in the **Password** field
3. Select **Login**



4. An email will be sent to your email address

5. Open the email and enter the **six-digit code** into the Two-Factor Authentication form.
6. Select **Verify.**
7. The code will expire after 20 minutes. If the code has expired or you haven't received the code via email, select Resend code.

6. select Verify

It is recommended that you change your password as soon as you have logged in for the first time.

Changing your password

To change your password:

1. Select the **Edit** tab
2. Enter your **Current password**
3. Confirm that your **E-mail address** is correct. Note this is a mandatory field.
4. Enter the **new Password**

   Note: the password must meet the following criteria:

   - minimum six (6) characters including
   - lowercase letters

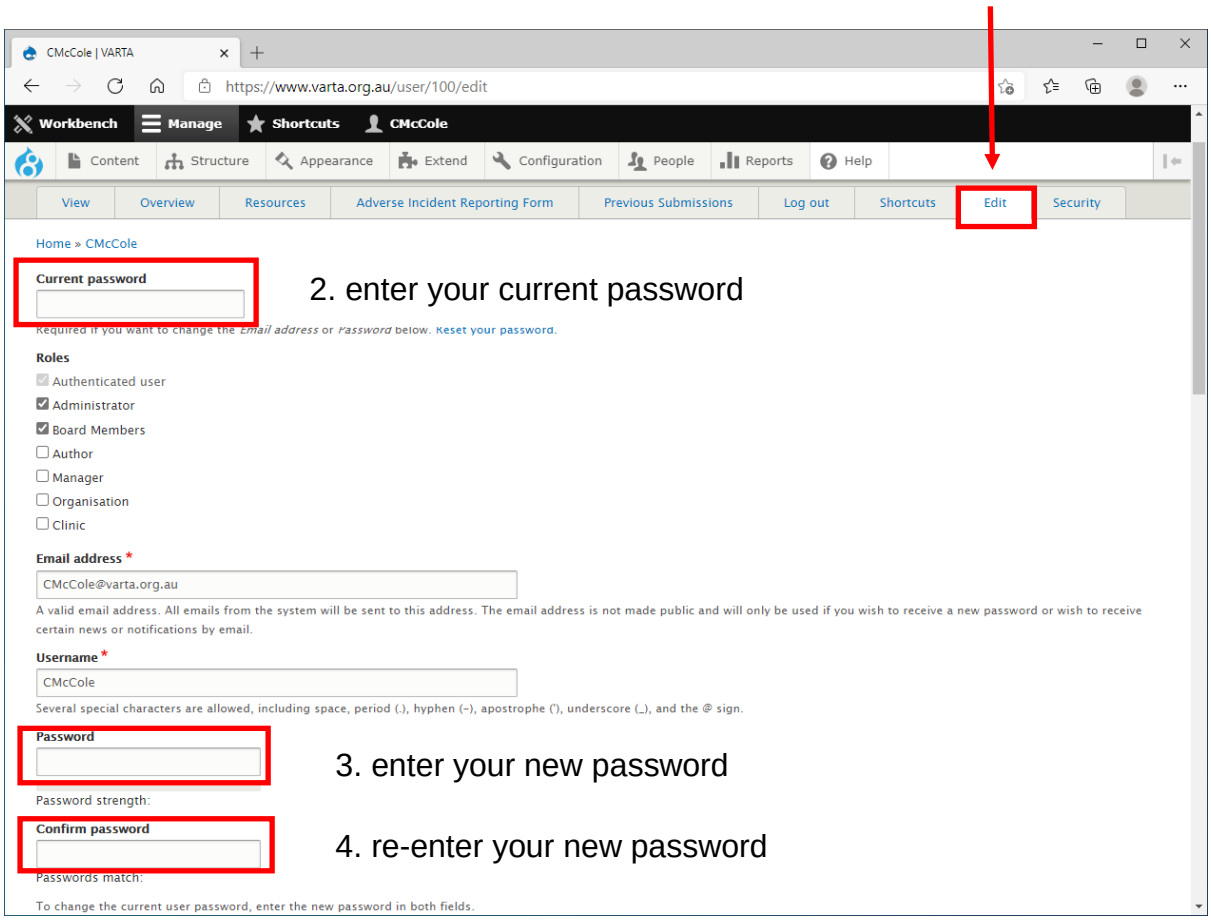
- uppercase letters
- numbers
- special characters (eg. $? @ & !)

The password strength will be displayed

5. Enter the new password again in the **Confirm password** field

A message will confirm that the password matches

1. select Edit to change your password



6. Select **Save** at the bottom of the screen

Completing the form

Please provide as much detail as possible when completing the Adverse Incident Reporting Form.

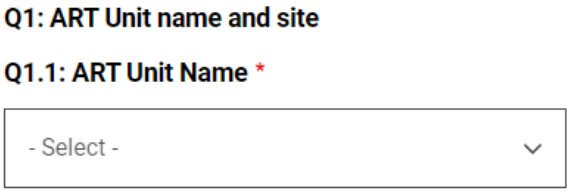
- Please note:

- Any attachments such as RiskMan reports can be uploaded at the end of the form.
- All fields indicated with an asterix (*) are mandatory.
- The session will expire after 30 minutes so you must complete your submission within this time.

1. To complete the form, enter the following information:

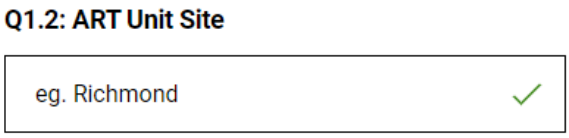
Q1.1 ART Unit Name*

2. The name of the ART Unit should be automatically populated. If not, select your ART Unit name from the drop-down list.



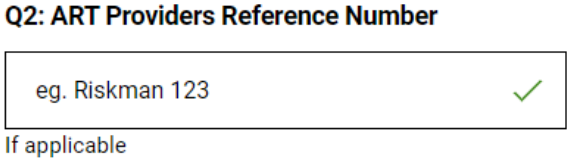
Q1.2 ART Unit Site

3. Enter the location of your ART Unit (e.g. Richmond)



Q2 ART Unit Providers Reference Number

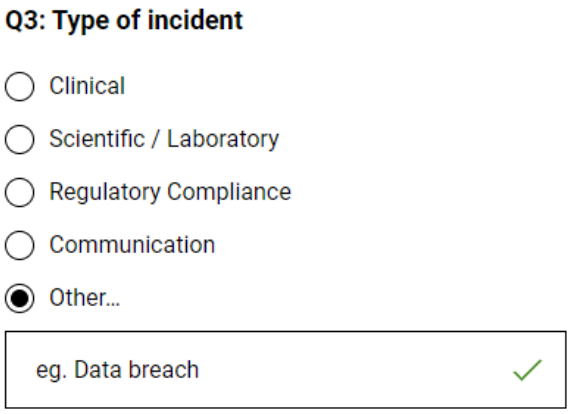
4. Enter your organisation's reference number for the incident (if applicable) (ie. Riskman reference number).



Q3 Type of incident

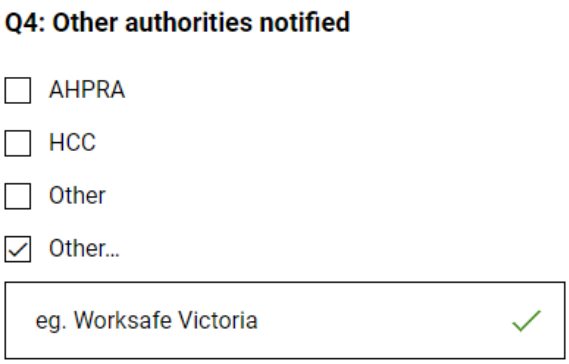
5. Click on the box to select the option that best describes the type of incident. For complex incidents, you may select more than one option.

6. If Other, please provide a brief description.



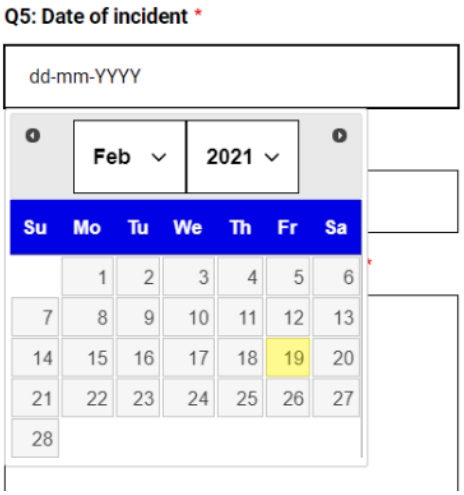
Q4. Other authorities notified

7. Click on the boxes to select which other authorities have been notified of the incident. You may select more than one option.
8. If Other, please list the names of any other agencies you have notified



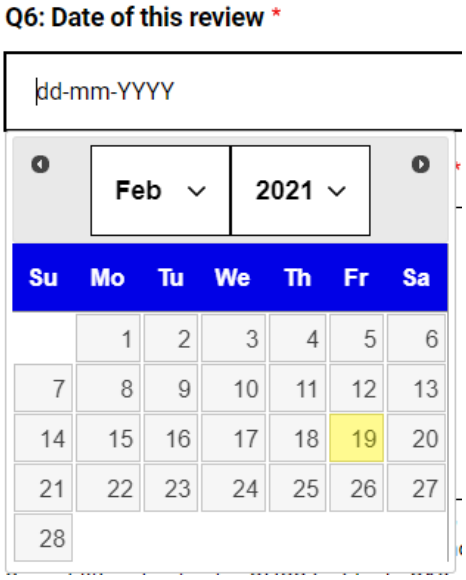
Q5. Date of incident*

9. Click on the calendar and select the date the incident occurred.



Q6. Date of this review*

10. Click on the calendar and enter the date the incident was reviewed



Q7. Incident description and summary*

11. Enter the details of the incident including:

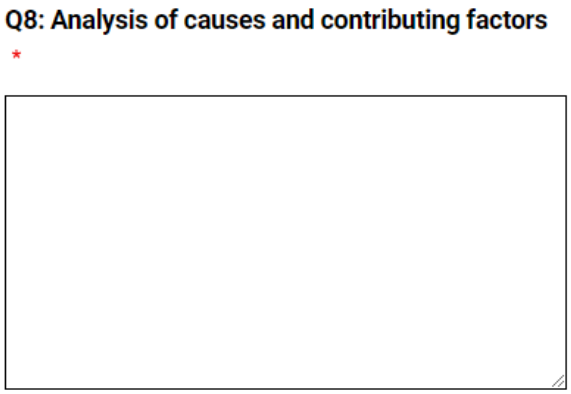
- what happened?
- who was affected? (ie. 24-year old female patient)
- what were the circumstances?
- what staff members were involved (don't provide names - just their position, ie. laboratory assistant)
- what was the severity of the incident?
- what was the outcome of the incident?

Q7: Incident description and summary *

Please include cause, how identified, severity, staff involved (not names, e.g. 2 embryologists) and dates. See additional notes for OHSS incidents Q12.

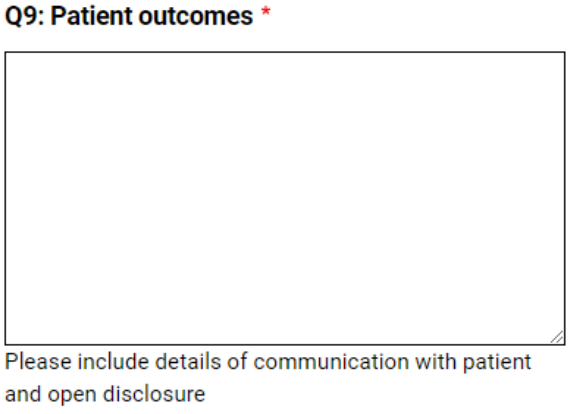
Q8. Analysis of causes and contributing factors*

12. Enter the details of what you believed caused the incident to occur and any factors that may have contributed to it.



Q9. Patient outcomes*

13. Enter the details of what information has been communicated to the patient or any other information disclosed.



Q10. Please enter the TOTAL number of days the patient was hospitalised

14. Enter the number of days the patient was hospitalised as a result of the incident (if applicable). Also include any hospital readmissions (if applicable).
15. Enter the number as whole days, ie. 7

Q10: Please enter the TOTAL number of days the patient was hospitalised:

ex: 23

If applicable. Include readmissions if they occurred.

Q11. Corrective action taken or planned to date

16. Enter the details of what corrective action has been taken or is planned to be taken.

Q11: Corrective action taken or planned to date

Q12. Date of conclusion of event

17. Click on the calendar and select the date that the matter was finalised including any corrective actions that occurred (or are anticipated to occur in the future)

Q12: Date of conclusion of event

dd-mm-YYYY

If applicable

Q13.1 Patient Age (years)

18. Enter the patient age at the time of the treatment

Q13: Patient and Treatment Details:

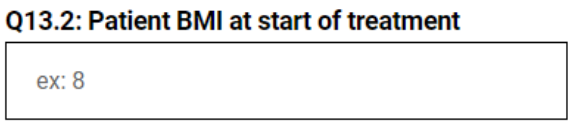
Please complete the following details about the patient and this treatment cycle:

Q13.1: Patient age (years) *

ex: 8

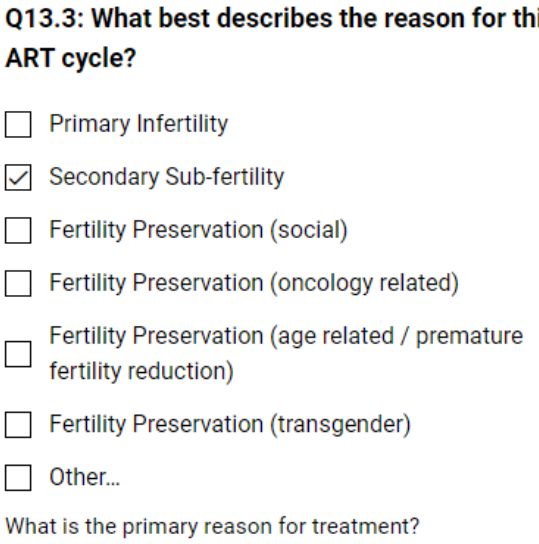
Q13.2 Patient BMI at start of treatment

19. Enter the patient's body mass index (BMI) at start of the treatment



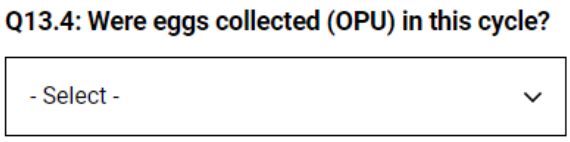
Q13.3. What best describes the reason for this ART cycle?

20. Select the main reason for this AFT cycle. If other, specify the reason.



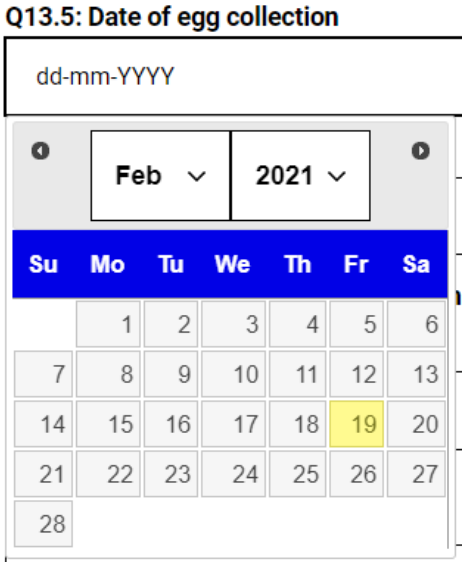
Q13.4. Were eggs collected (OPU) in this cycle?

21. Select YES or NO from the drop-down list.



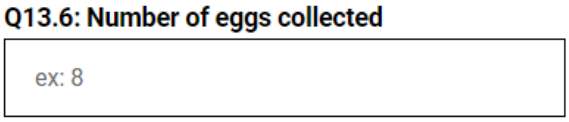
Q13.5 Date of egg collection

22. Click on the calendar and enter the date of the egg collection.



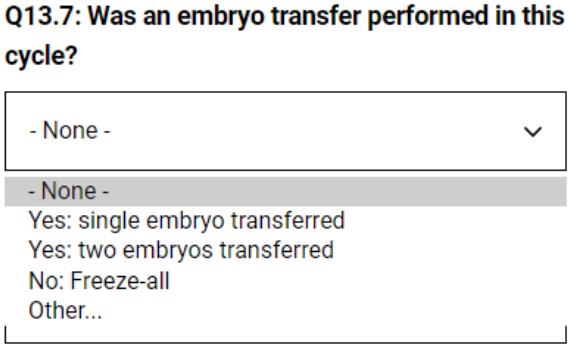
Q13.6 Number of eggs collected

23. Enter the number of eggs collected



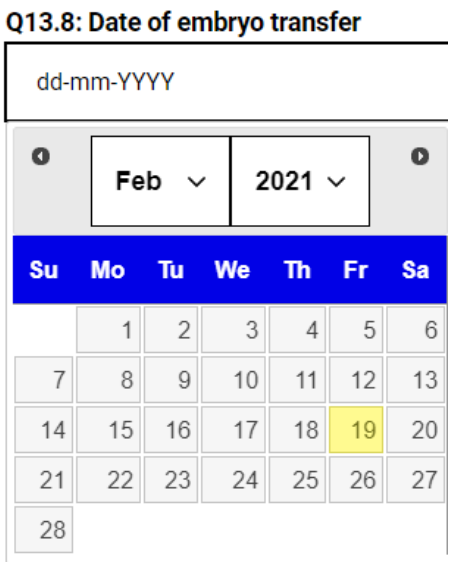
Q13.7. Was an embryo transfer performed in this cycle?

24. Select the relevant option from the drop-down list. If other, please specify what occurred.



Q13.8 Date of embryo transfer

25. Click on the calendar and enter the date of the embryo transfer



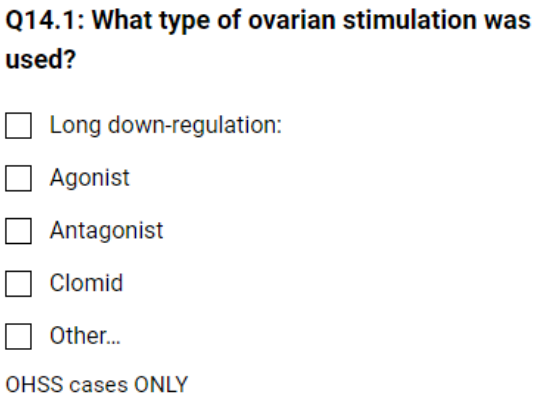
Q14. OHSS reporting only

26. Only complete this section if:

- the incident involved OHSS that resulted in an overnight hospital admission (excluding hospitalisation only for observation or intravenous fluids after symptoms);
  OR
- the incident involved a severe or critical case of OHSS as defined by the RCOG classification of severity

Q14.1 What type of ovarian stimulation was used?

27. Click on the box to select they type of ovarian stimulation that was used. If other, enter the name of the stimulation used.



Q14.2 What type of ovulation trigger was used

28. Click on the box to select the type of ovulation trigger that was used. If other, enter the type of trigger used.

Q14.2: What type of ovulation trigger was used?

- [x] HCG
- [ ] Rec-LH
- [x] Agonist
- [ ] Dual Trigger
- [ ] Other...

OHSS cases ONLY

Q14.3 Please state the type and dose of ovulation trigger used

29. Enter the name of the ovulation trigger and dose used

Q14.3: Please state the type and dose of ovulation trigger used

For example Ovidrel 250, hCG 500, etc...

Q14.4 What type of FSH was used

30. Click on the box to select the type of FSH that was used. If other, enter the details of the other type of FSH used.

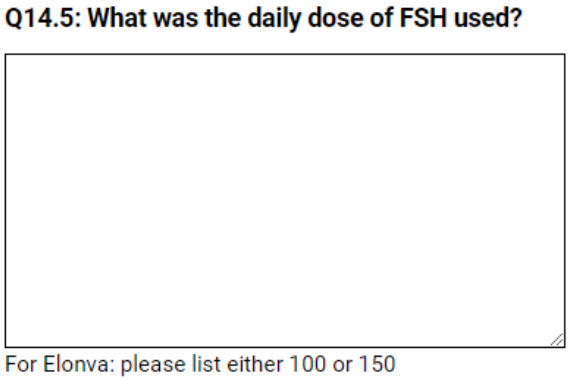
Q14.4: What type of FSH was used?

- [ ] Bemfola
- [ ] Elonva
- [ ] Glonal F
- [ ] Other...

OHSS cases ONLY

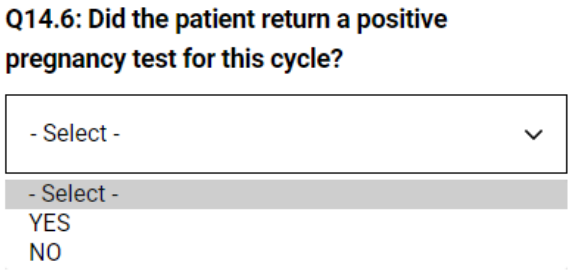
Q14.5 What was the daily dose of FSH used?

31. State the details of the daily dose of FSH used



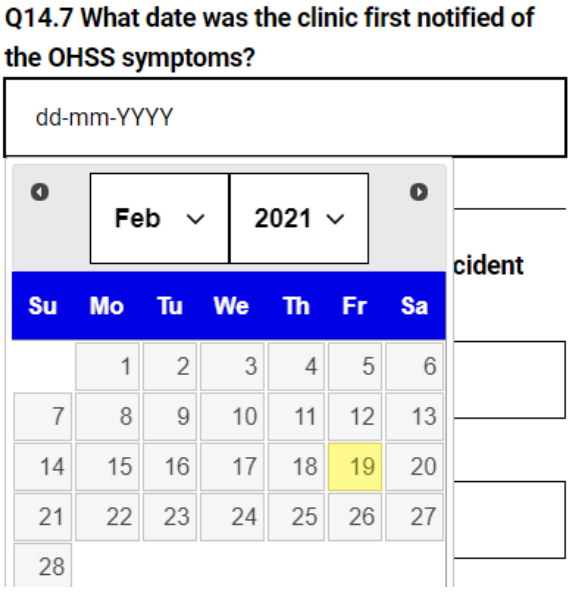
Q14.6 Did the patient return a positive pregnancy test for this cycle?

32. Select YES or NO from the drop-down list



Q14.7 What date was the clinic first notified of the OHSS symptoms?

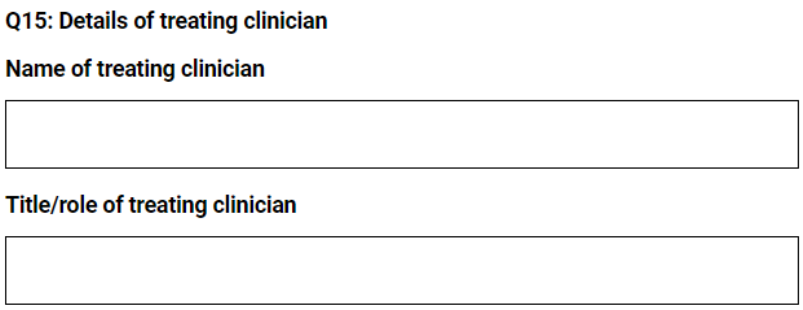
33. Click on the calendar and select the date the clinic was first notified of OHSS symptoms



Q15. Details of treating clinician

34. Enter the details of the treating clinician including:

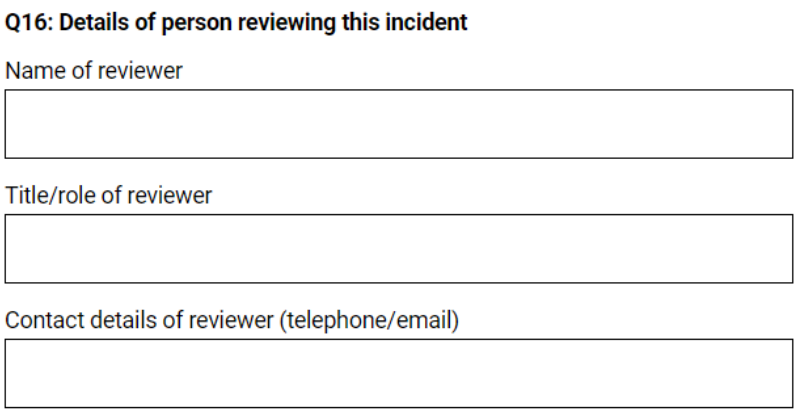
- Name
- Title / role



Q16. Details of person reviewing this incident

35. Enter the details of the person who reviewed the incident (ie. Medical Director or supervisor) including:

- Name
- Title / role
- Contact details (telephone number or email address)

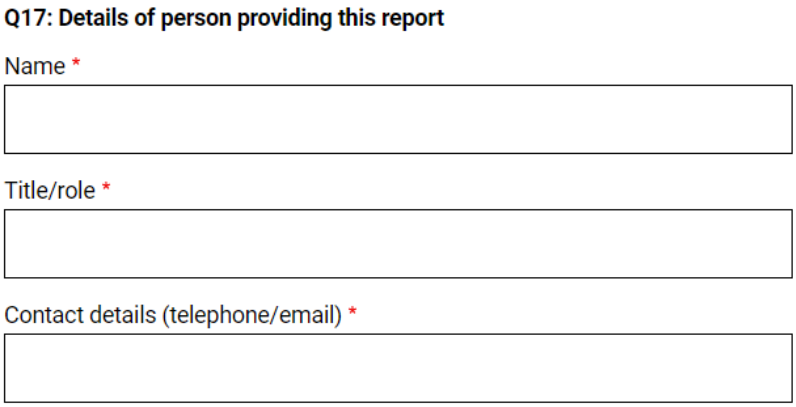


Q17. Details of person providing this report

36. Enter the details of the person providing this report including:

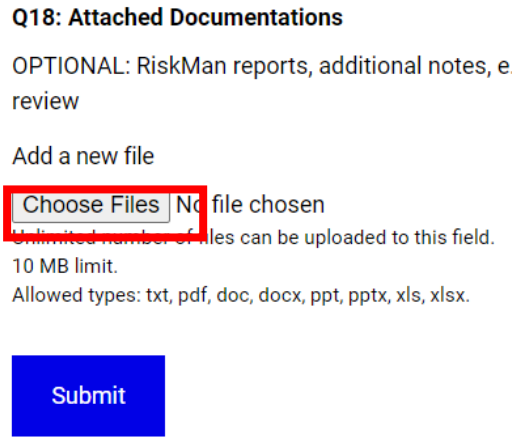
- Name
- Title / role
- Contact details (telephone number or email address)

37. If you are the person providing the report, the system will automatically enter your Name and email address in the form.
38. If you are entering the report on behalf of someone else, you may overwrite this information and enter their details instead.



Q18. Attached Documentation

39. Click on the Choose Files button to upload any documents that you wish to attach
40. Select **Upload**



Please Note:

- You may upload multiple documents
- For security reasons, you cannot upload images or picture files (ie. jpg, bmp)

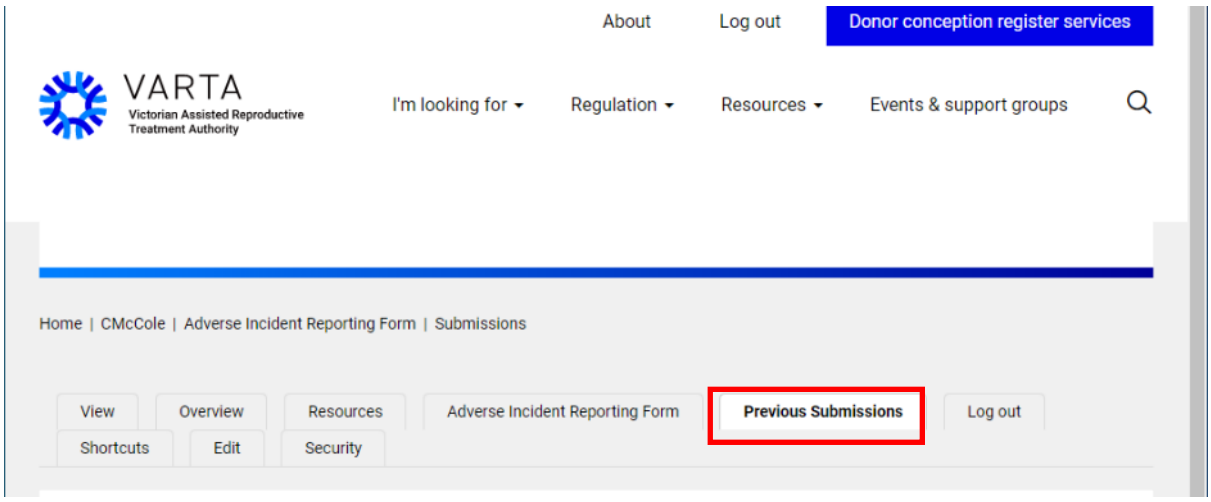
41. Click on the **Submit** button to send the form to RTAC, VARTA and the RTAC Auditor (either Global Mark or DNV).
42. You should receive the following message once you have submitted a form:

43. A confirmation email will also be sent to your email address confirming submission of the form.

Viewing Adverse Incident forms submitted

To view a list of Adverse Incident forms that you have previously submitted:

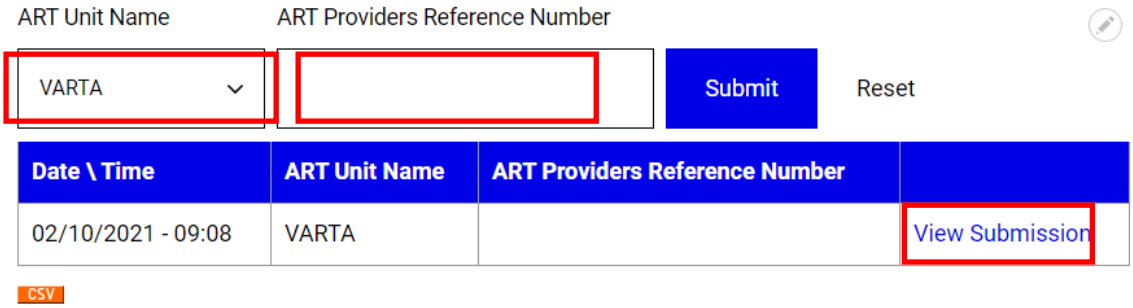
1. Select the **Adverse Incident Reporting Form**
2. Select the **Previous Submissions** tab



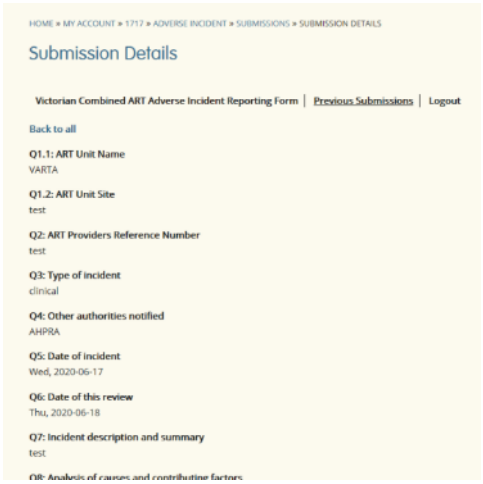
A list of previous submissions will be displayed

Note: you will only be able to view reports that you have submitted. **RTAC** will be able to view reports submitted by all ART clinics and can filter on the ART Unit Name in addition to the ART Reference Number.

3. To filter on a particular **ART Reference Number**, type in the number in the ART Reference Number field and click Submit



4. To view the report, select **View Submission**
5. The report will be displayed

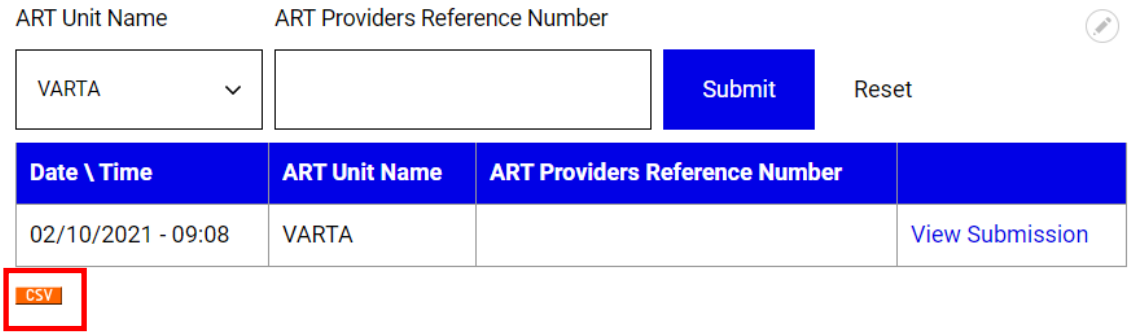


6. To view the full list again, click **Previous Submissions** and select **Reset**

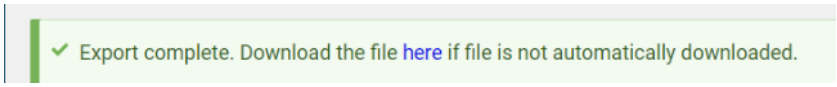
Exporting Adverse Incident forms

To export a list of Adverse Incident forms that you have previously submitted:

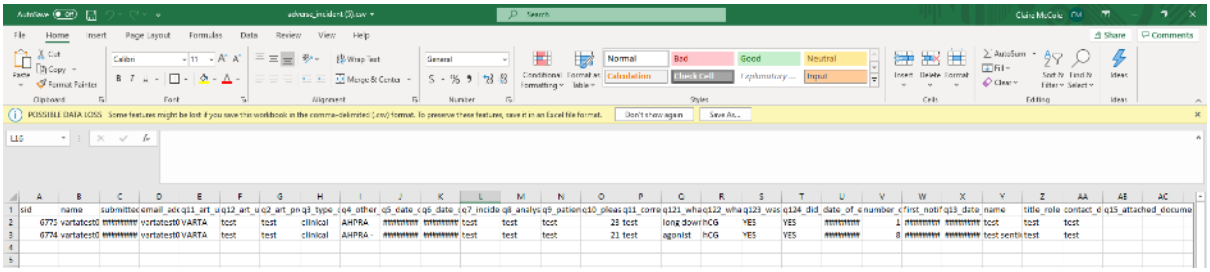
1. Follow steps 1-2 in the Viewing Adverse Incident forms submitted section above.
2. Click **Export CSV**



3. The following messge will display:



4. Click ‘here’ to open the link. The file may also appear in a pop-up window. Click Open file to view the file
5. The export will open in a MS Excel spreadsheet

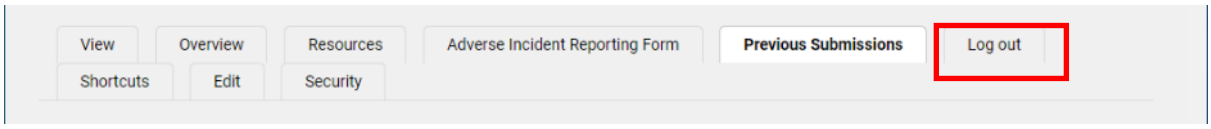


6. Save the spreadsheet to keep a copy of the file.

Logging out

To log out once you have submitted the form:

1. Select the **Adverse Incident Reporting Form**
2. Select the **Logout** tab



Help and Support

If you have any questions, please contact the VARTA Regulation Team on regulation@varta.org.au or (03) 8601 5250.

Technical and Security Specifications

The Adverse Incident Reporting Form complies with the Victorian Government's Information Management Framework and Cyber security standards and guidelines.

System Details

The Adverse Incident Reporting Form is hosted on the VARTA website which uses a Drupal CMS with regular maintenance and security updates. A separate Pantheon environment is used for development and testing of the system.

The system is hosted by Sentius (https://www.sentiussystems.com/) in Australia and utilises the following data storage and security systems:

- Sentius cloud containers managed through Pantheon hosting management (runs on Google Cloud (https://cloud.google.com/security)
- Security specifications (https://pantheon.io/security)
- HTTPS (https://pantheon.io/docs/https)
- Data storage – databases are encrypted at rest and disk-level
- Service & security protection monitoring
- 2-factor authentication (2FA)
- Hardware firewall
- Malware scanning/removal
- Automated daily backups with one month retention
- Secure Sockets Layer (SSL) Certificates.

The system is administered by VARTA's external IT support / maintenance provider Outright IT (https://www.outrightit.com.au/)

Penetration Testing

The portal has undergone rigorous penetration testing by an independent information technology security agency. This testing included a simulated cyberattack against the system which found that there were no high-risk security vulnerabilities. Routine penetration testing will be undertaken to mitigate any new risks identified.

The system is administered by VARTA and security permissions have been applied to partition each ART provider's information to ensure that reports remain confidential and are not able to be accessed by other clinics. See Roles and Responsibilities for further information.

Frequently Asked Questions (FAQs)

Sharing user accounts

Q. Can I share my user account details with another colleague from my clinic?

A. No. You must not share your username and password with any other staff members. All staff who need to use the system must apply for their own account.

Modifying details after submitting the form

Q. Can I change the details in a report such as add or remove text or upload additional documents once I have submitted the Form?

A. No. For data integrity reasons, Adverse Incident Report Forms cannot be modified once they have been submitted. If you have made a mistake and need to correct an error or have left something out, please notify the VARTA Regulation Team of the details that needs to be changed. Alternatively, you may submit a new Form and submit a request to regulation@varta.org.au for the original Form be cancelled. Any new submissions will be automatically forwarded to RTAC.

Deleting a form after it has been submitted

Q. Can I delete a report after it has been submitted?

A. No. For data integrity reasons, Adverse Incident Report Forms cannot be deleted once they have been submitted. If you have made a mistake and need to cancel the form, please submit a request to the VARTA Regulation Team. Alternatively, you may submit a new Form and submit a request to regulation@varta.org.au for the original Form be cancelled. VARTA will notify RTAC that the original form has been deleted and any new submissions will be automatically forwarded to RTAC.

Information sharing

Q. Can other clinics see the Adverse Incident Report Forms that I have submitted?

A. No. Each clinic has its own secure area within the portal. Staff can only see reports submitted in relation to their own clinic. Information submitted is only available to VARTA and RTAC and is not shared with the other clinics. For further details on information security see Roles and Responsibilities.

Information security

Q. How secure is the system? Is the information protected from data breaches, hackers and cyber-attacks?

A. The Adverse Incident Reporting portal complies with the Victorian Government's Information Management Framework and Cyber security standards and guidelines. It has also undergone rigorous penetration testing to confirm it does not have any security vulnerabilities. Penetration testing will also be undertaken on a routine basis to mitigate any new risks identified. For further details on information security see Technical and Security Specifications.

Reporting to RTAC or VARTA

Q. Can I submit my report just to RTAC and not VARTA (or vice versa)?

A. No. All reports are submitted to both RTAC and VARTA. This is to simplify the reporting process and to ensure that the same information is provided to both agencies.

Time savings

Q. Will the new Adverse Incident reporting portal save time?

A. Yes. In the past ART providers had to submit two reports: one to RTAC and another to VARTA. This on-line form is designed to be a ‘one-stop-shop’ covering the reporting requirements of both RTAC and VARTA. This means less paperwork and administration for you.