# Training on Medical Device Information System (MDIS)

## PART III: REPORTING OF MEDICAL DEVICE SAFETY ALERTS AND ADVERSE EVENTS

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# Agenda

1) Functionalities in Trader User Interface
2) Functionalities in Individual User Interface
   - General functions
   - Report Medical Device Safety Alerts
   - Report Medical Device Adverse Events
   - Other reporting-related matters
3) Enquiry and Support

# 1) Functionalities in Trader User Interface

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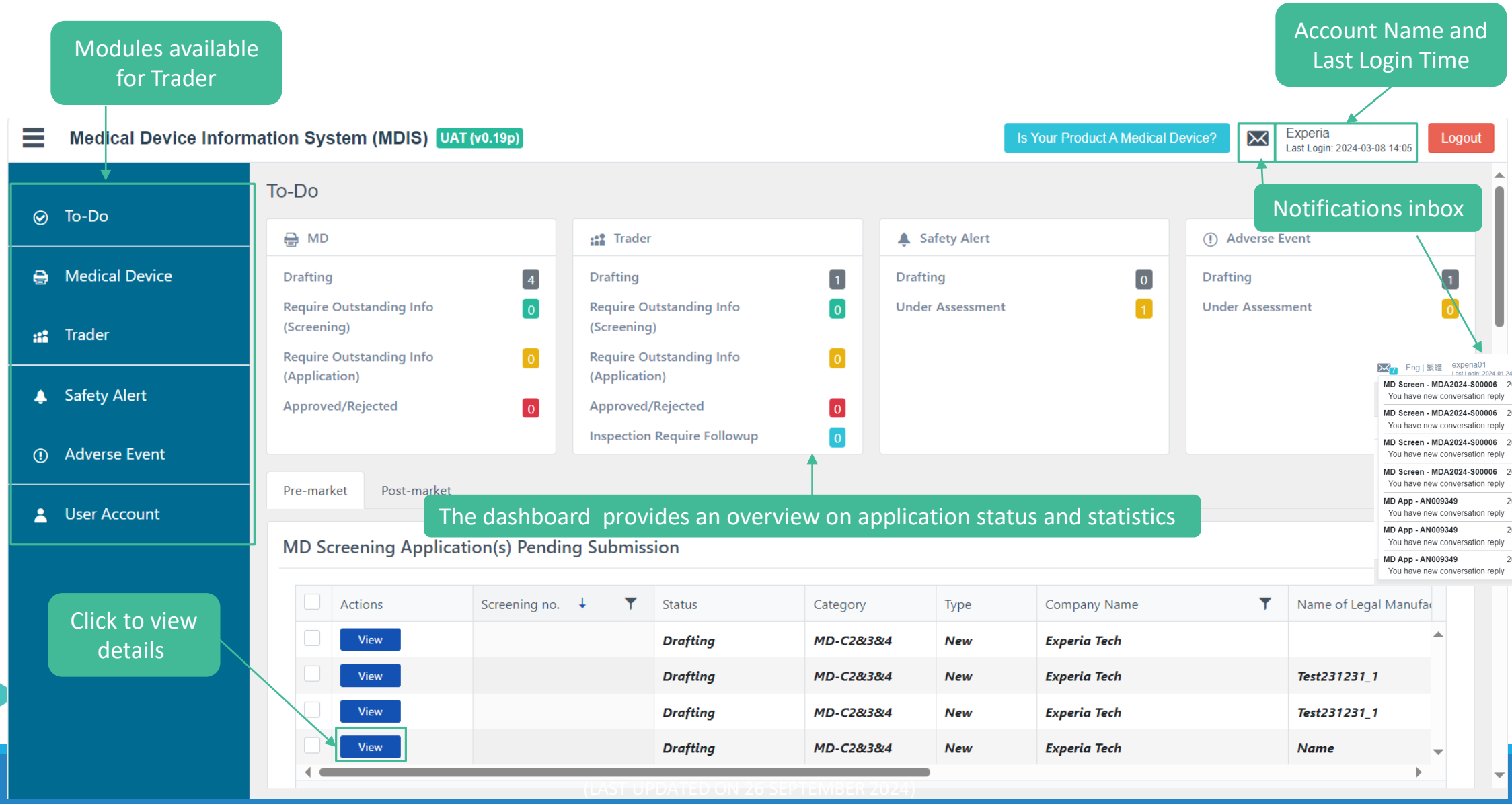
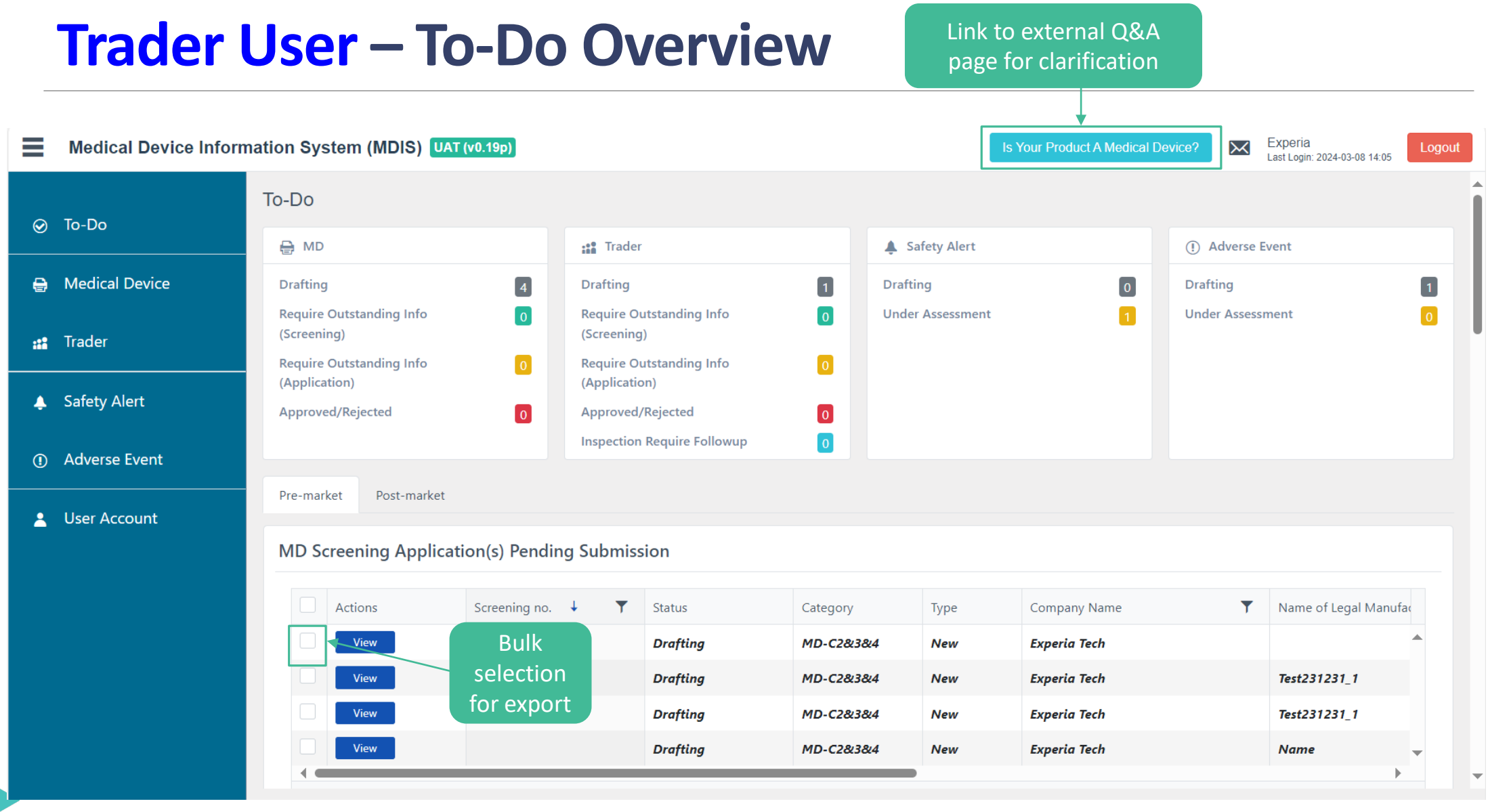
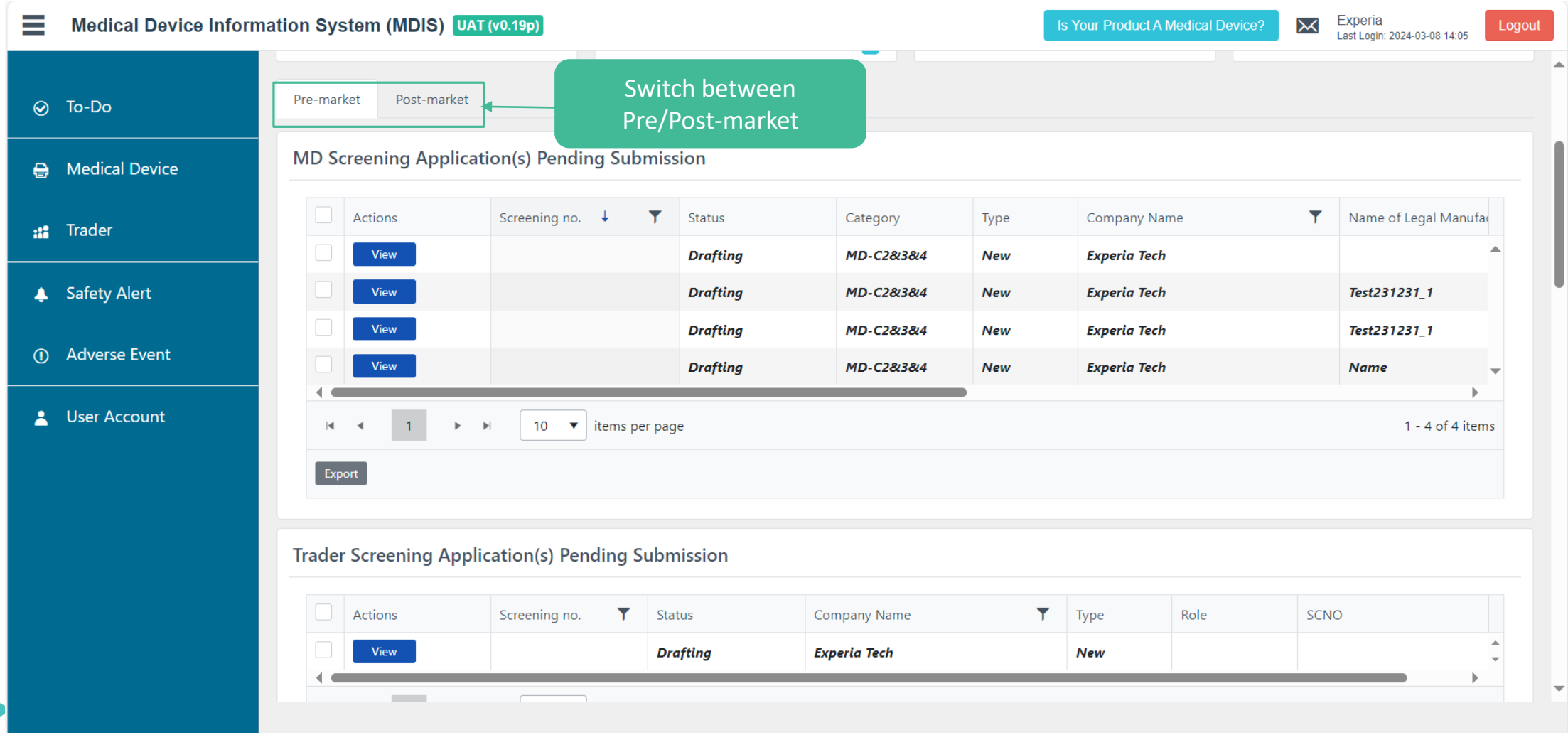
# Trader User – To-Do Overview



# Trader User – To-Do Overview



# Trader User – To-Do Overview

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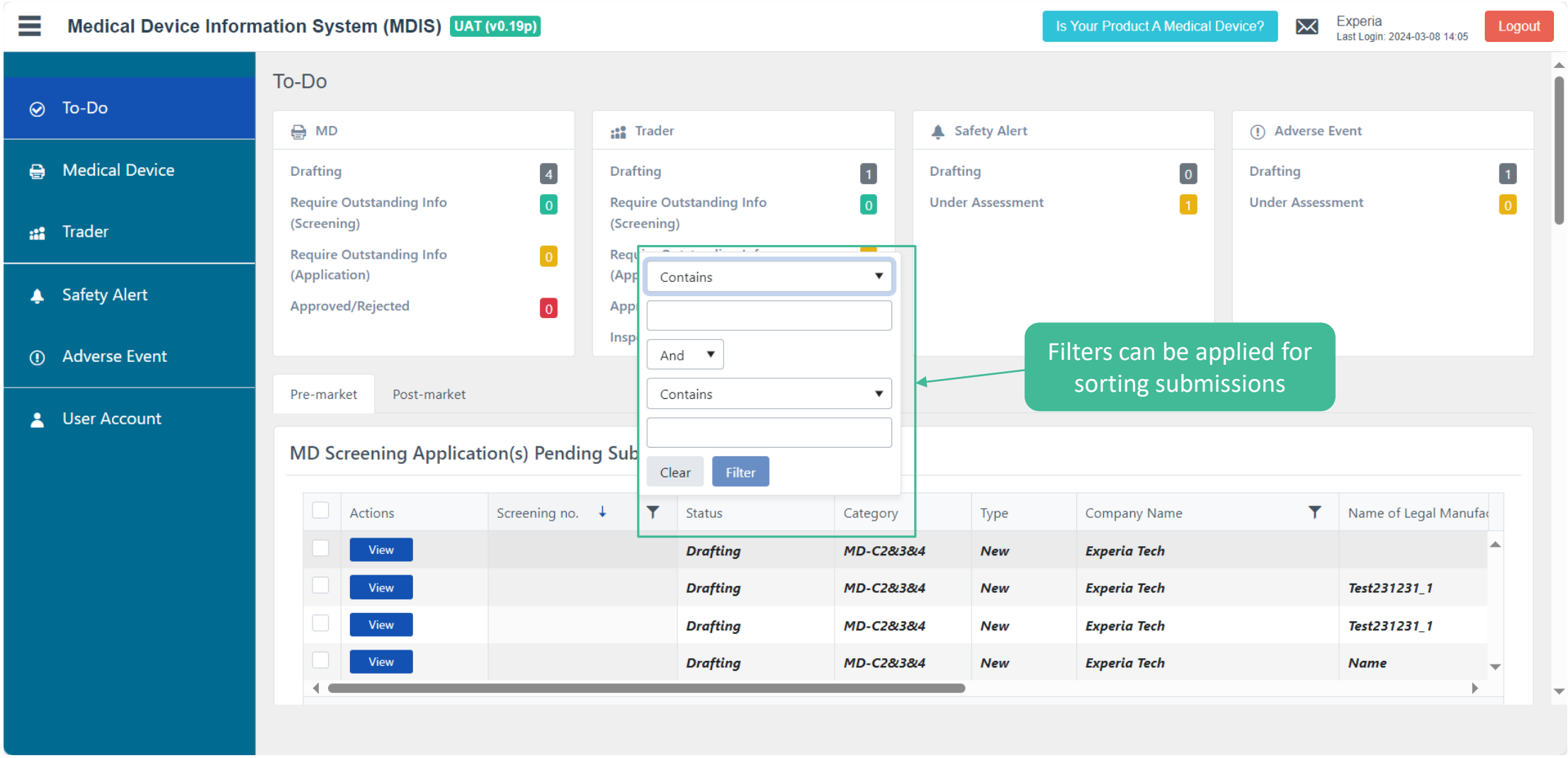
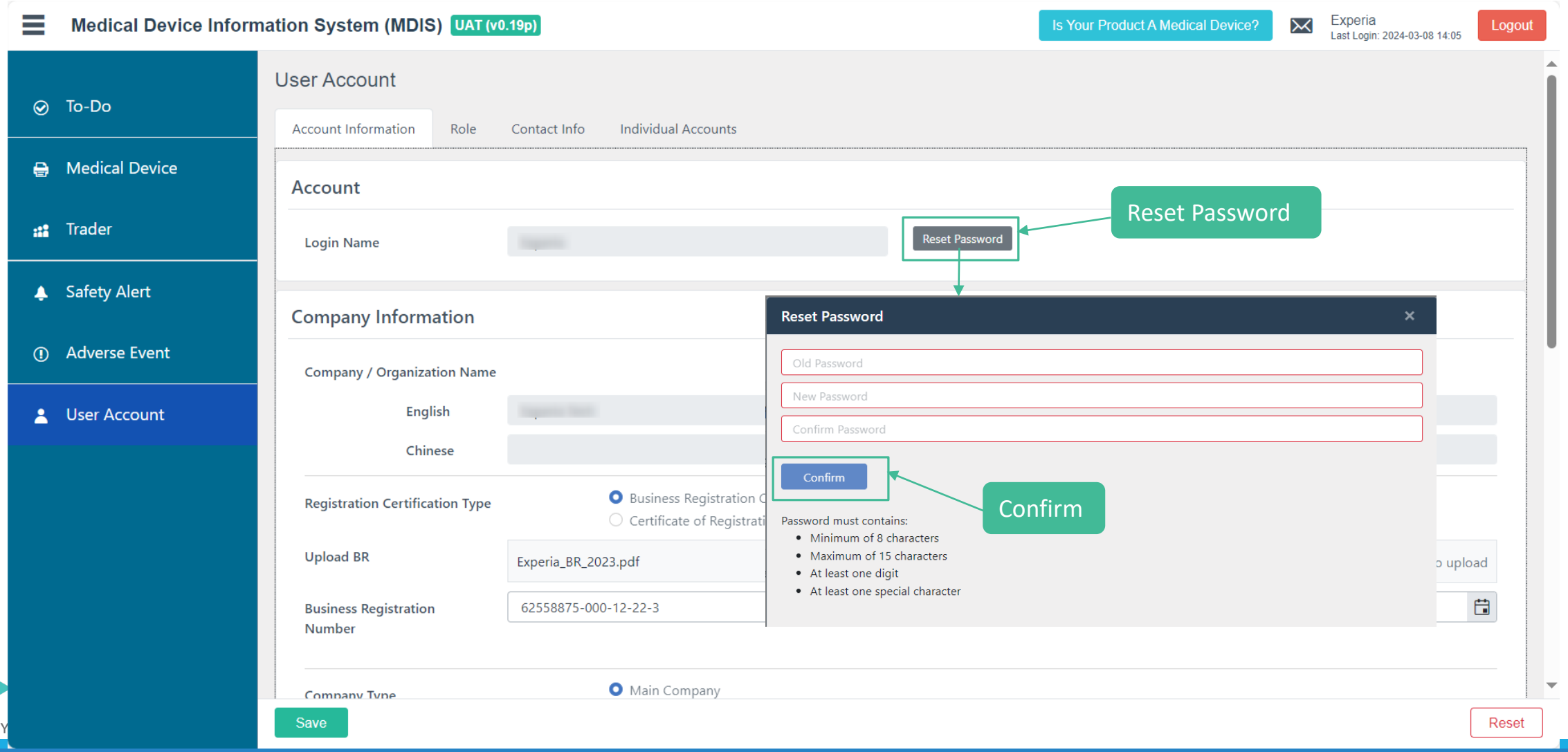
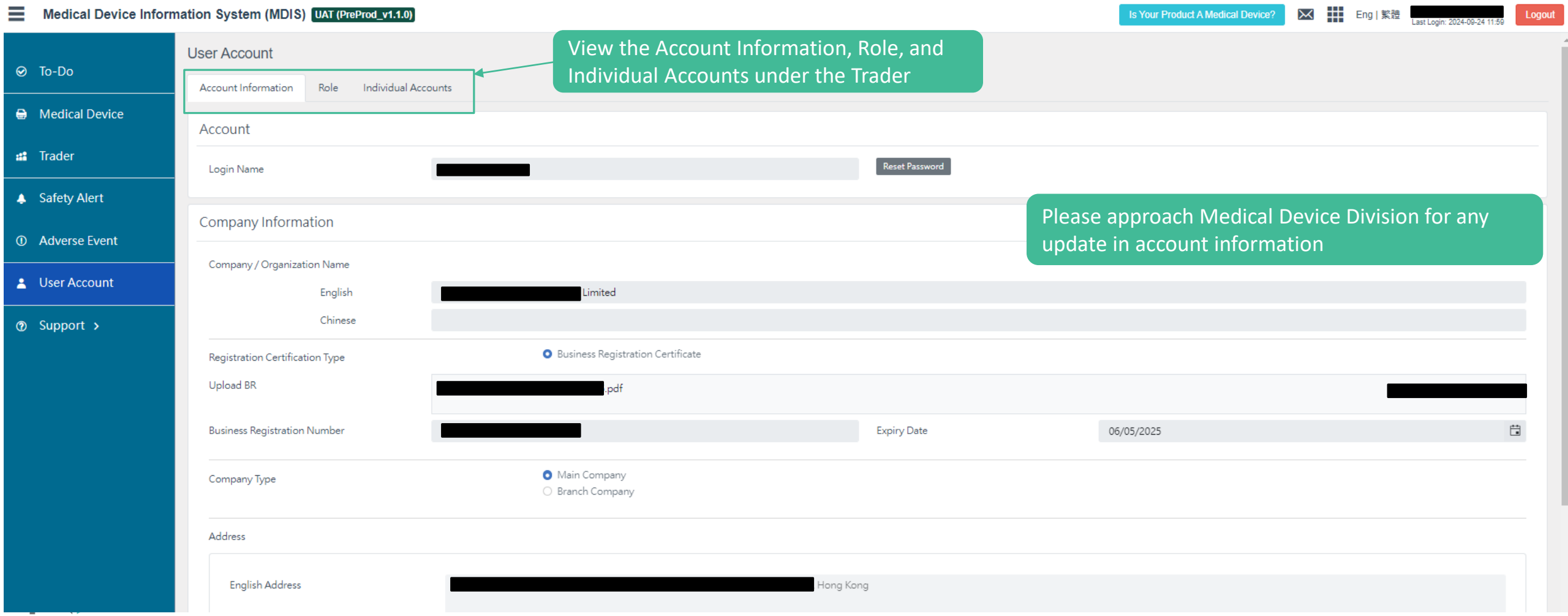
# Trader User – To-Do Overview



# Trader User – User Account Management – Reset Password



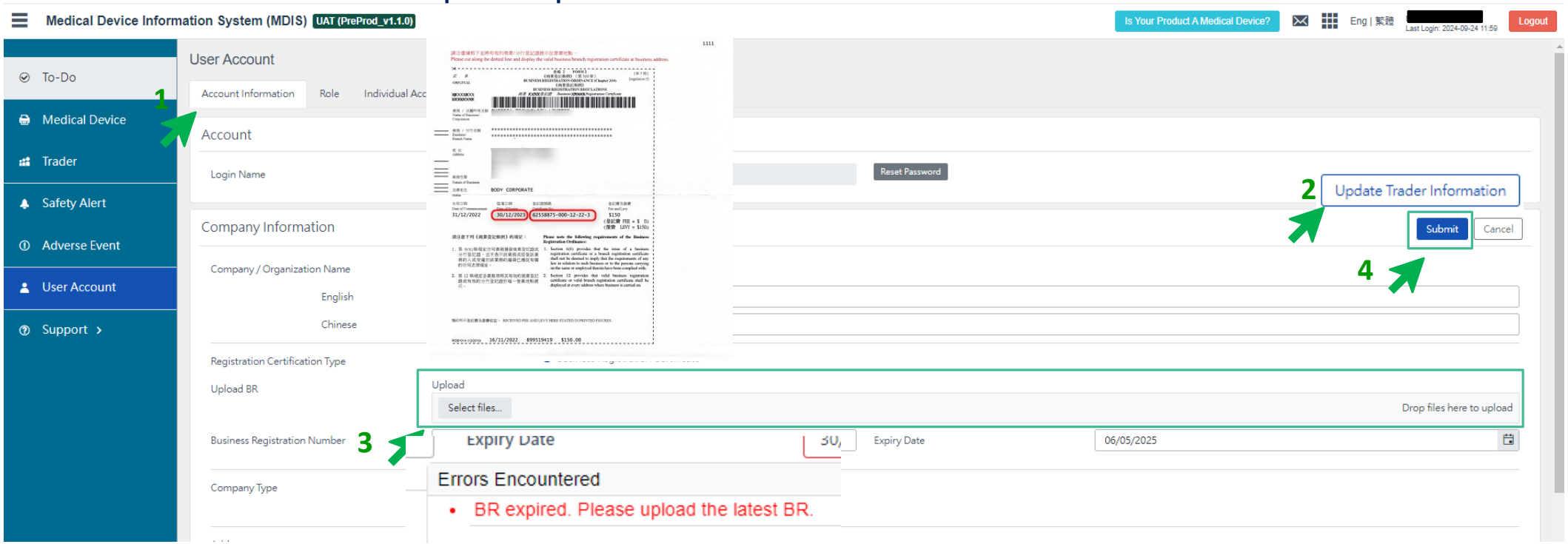
# Trader User – User Account Management



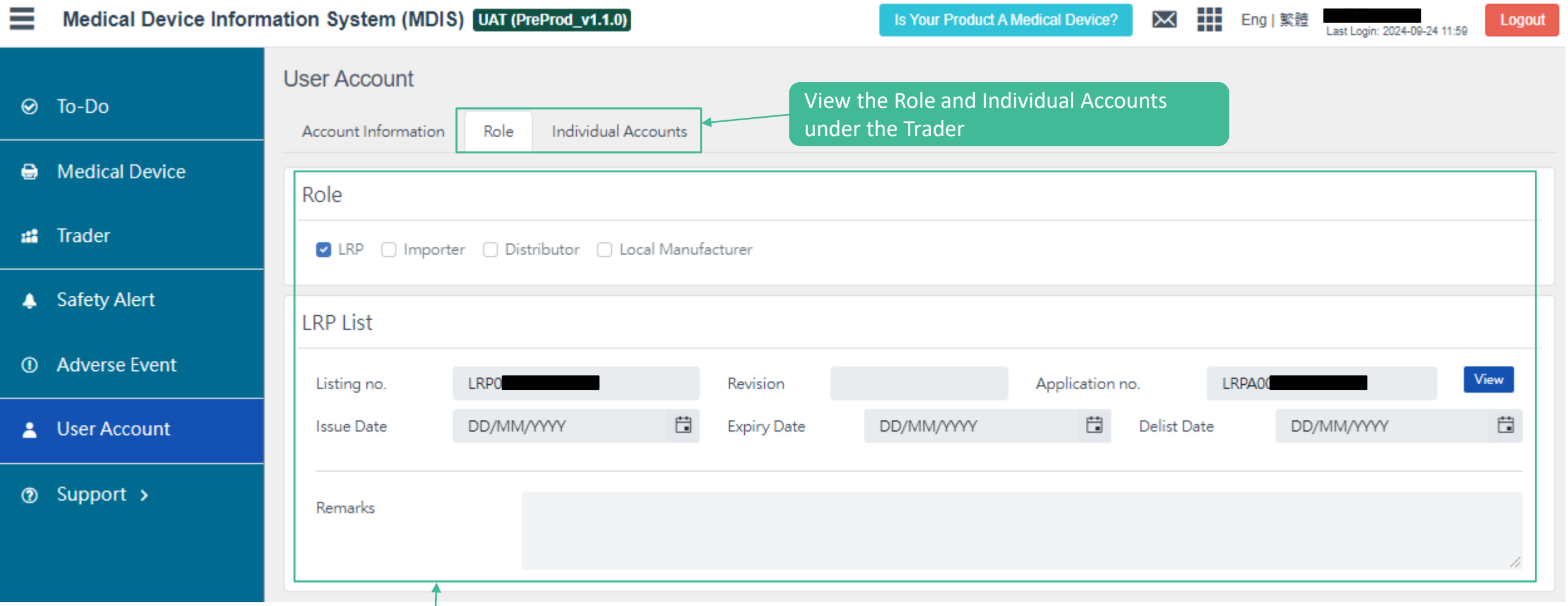
# Trader User – User Account Management – Upload BR

To maintain account operation, you would need to upload latest BR regularly.

1. Select “**User Account**” > “**Account Information**”
2. Click “**Update Trader Information**”
3. Upload BR file (The Business Registration Number and Expiry Date will be automatically recognized and filled. Validation check applies to the expiry date)
4. Click “**Submit**” to complete upload



# Trader User – User Account Management

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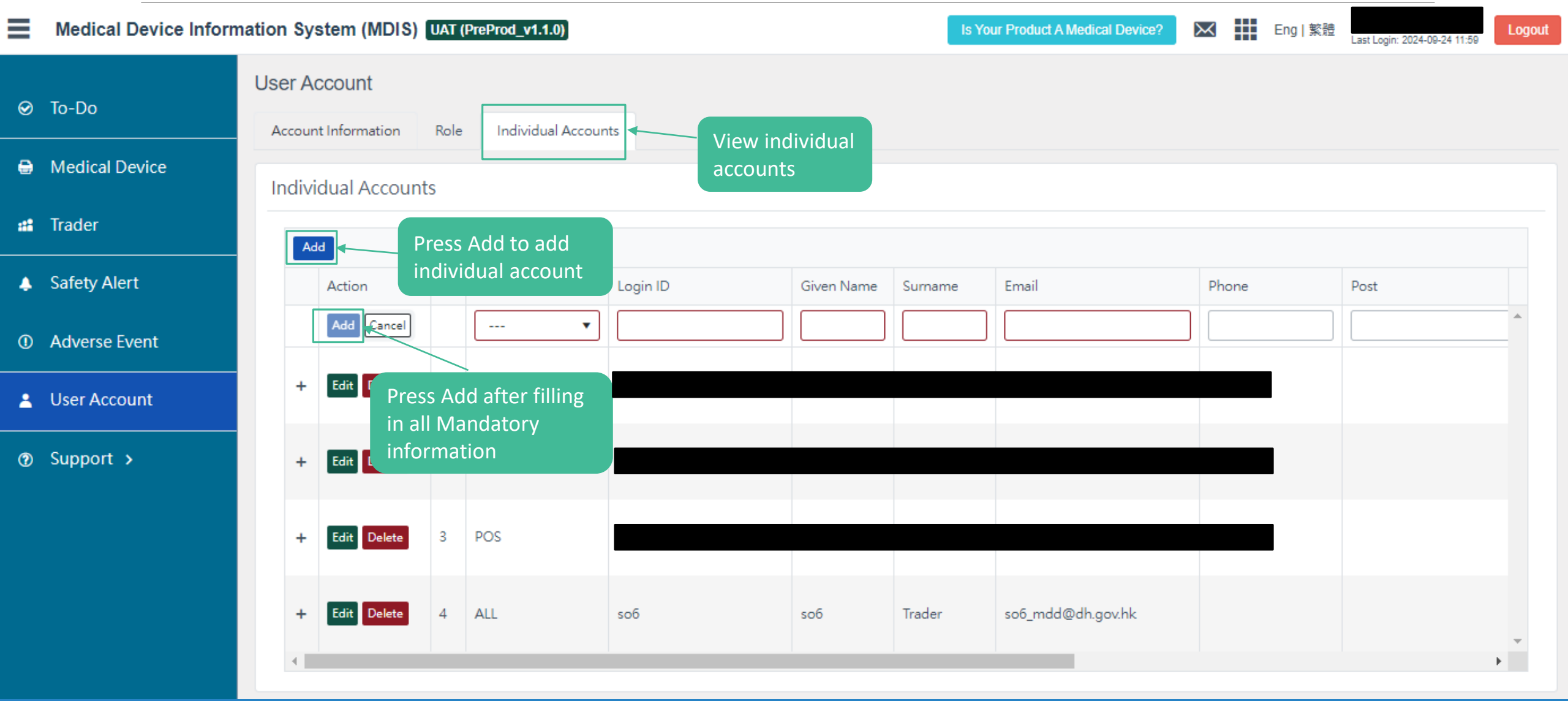
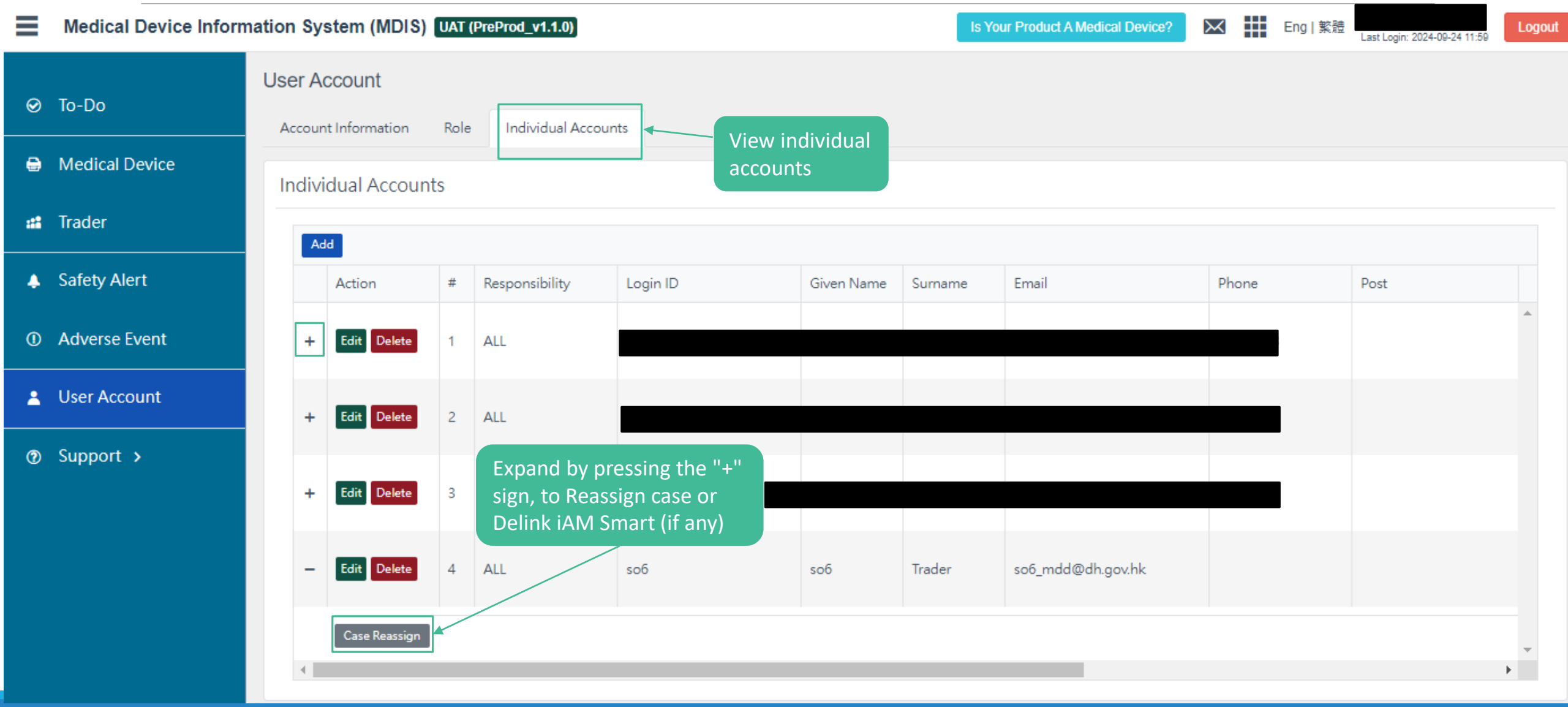
# Trader User – User Account Management – Add Individual Accounts



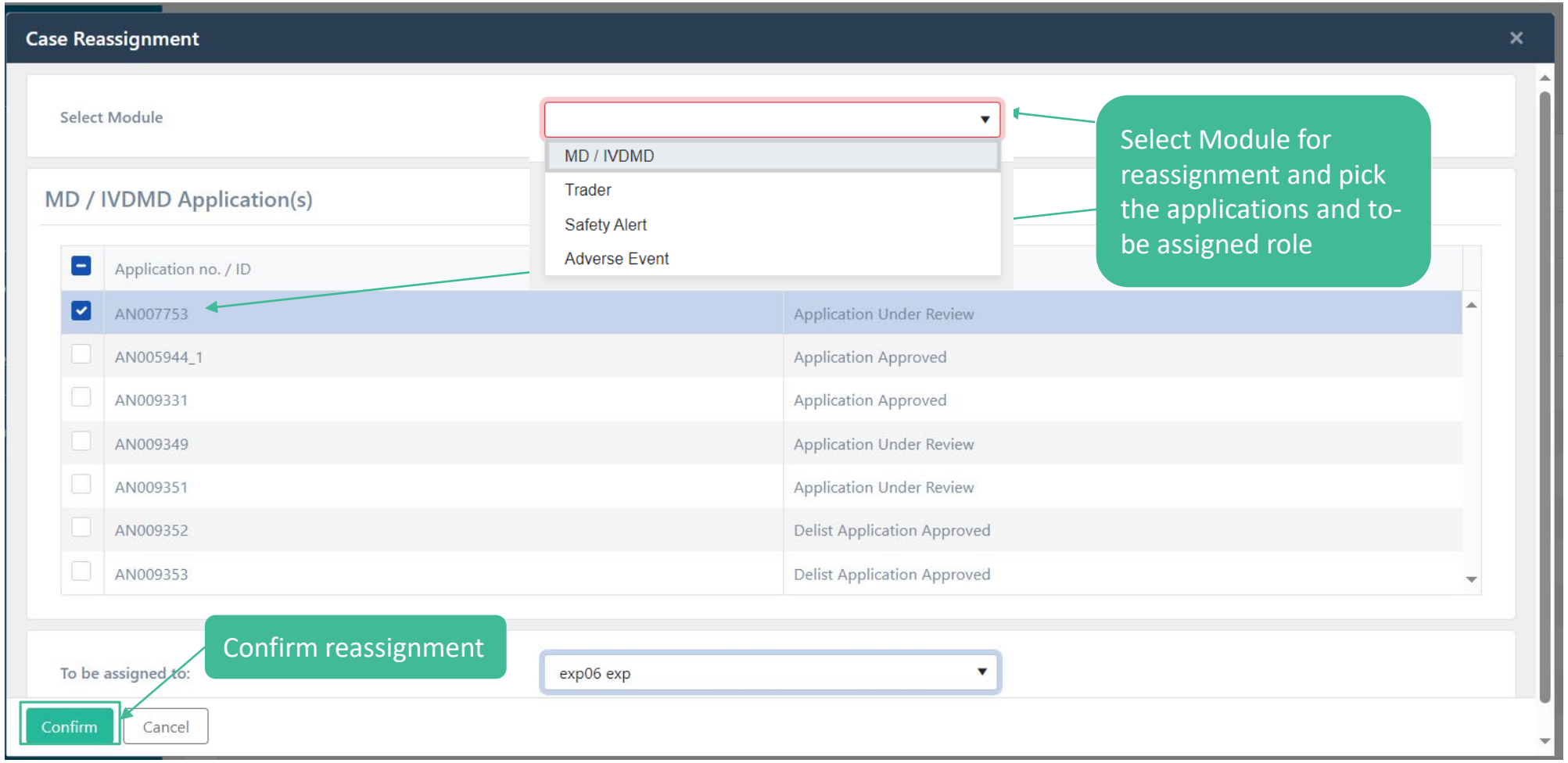
# Trader User – User Account Management – Case Reassign



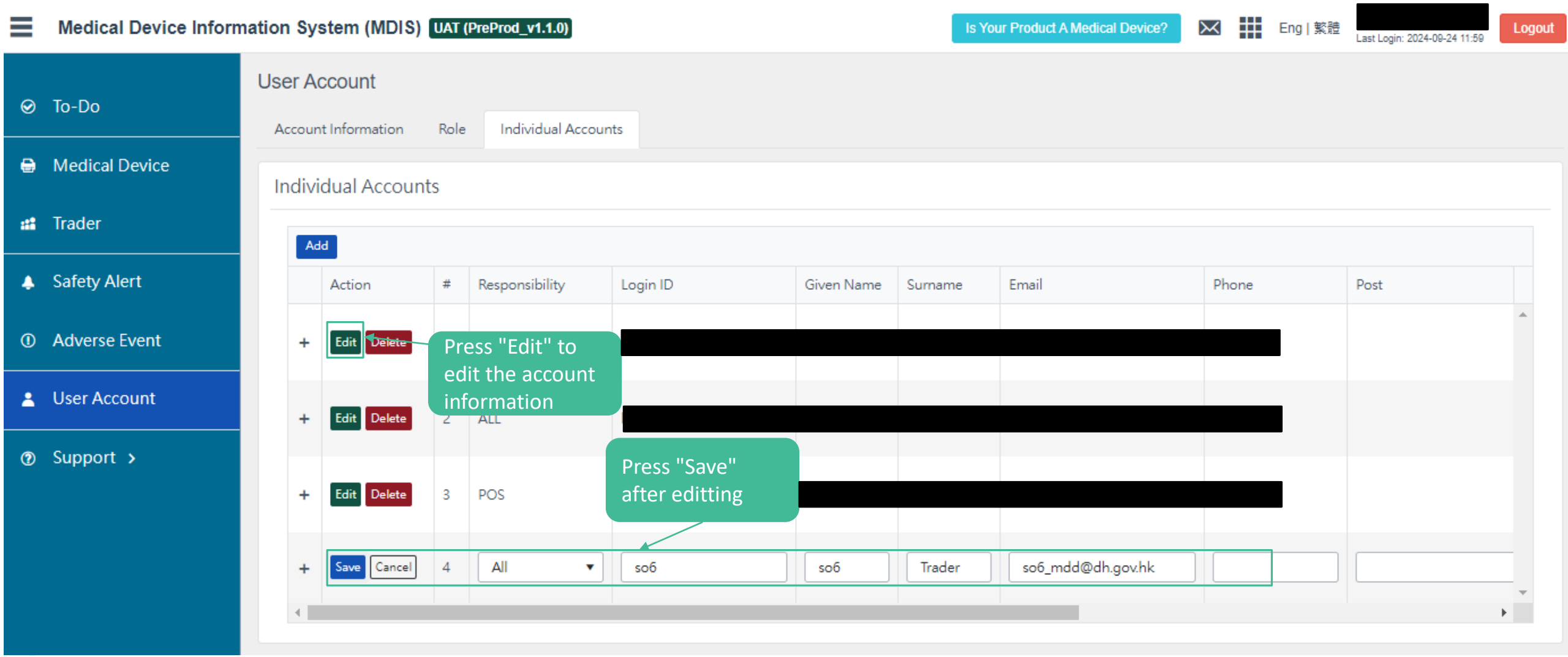

(LAST UPDATED ON 26 SEPTEMBER 2024)

# Trader User – User Account Management – Case Reassign

Only responsible Individual accounts can submit change / renewal / delist applications for their assigned application numbers



# Trader User – User Account Management – Edit account information

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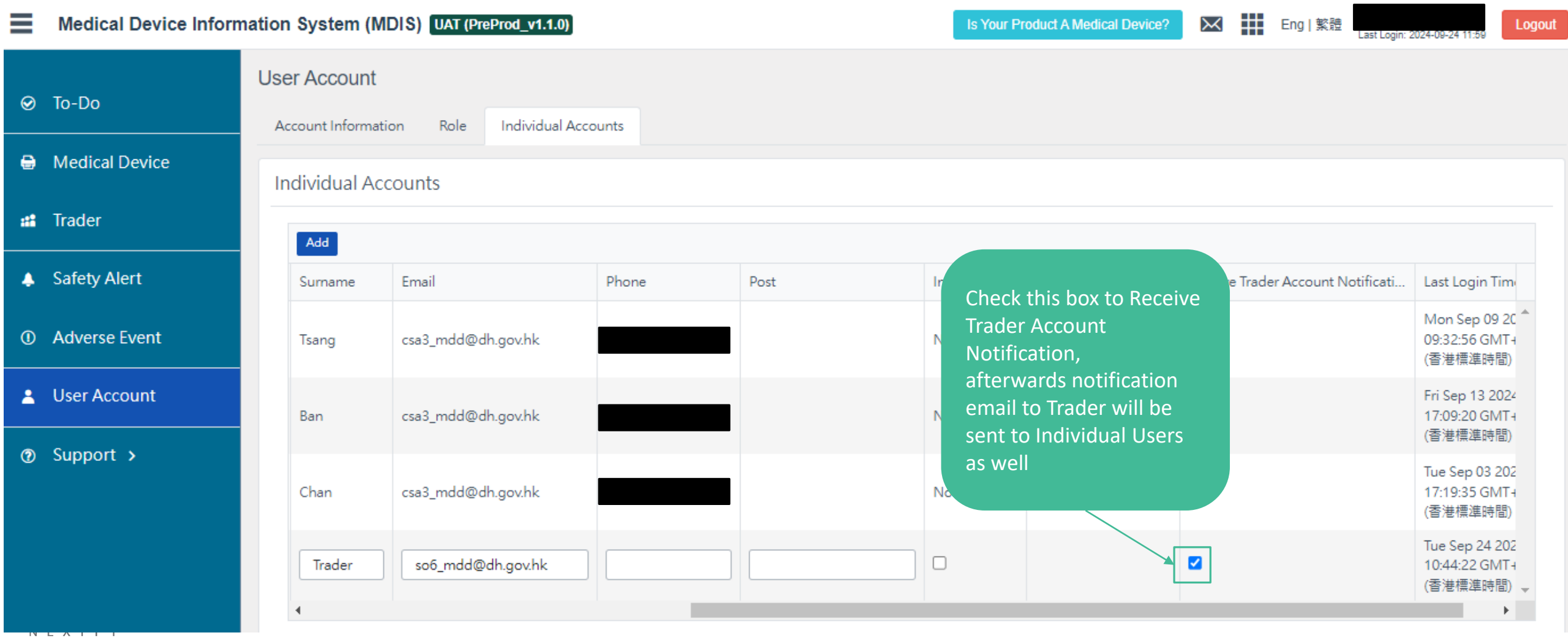
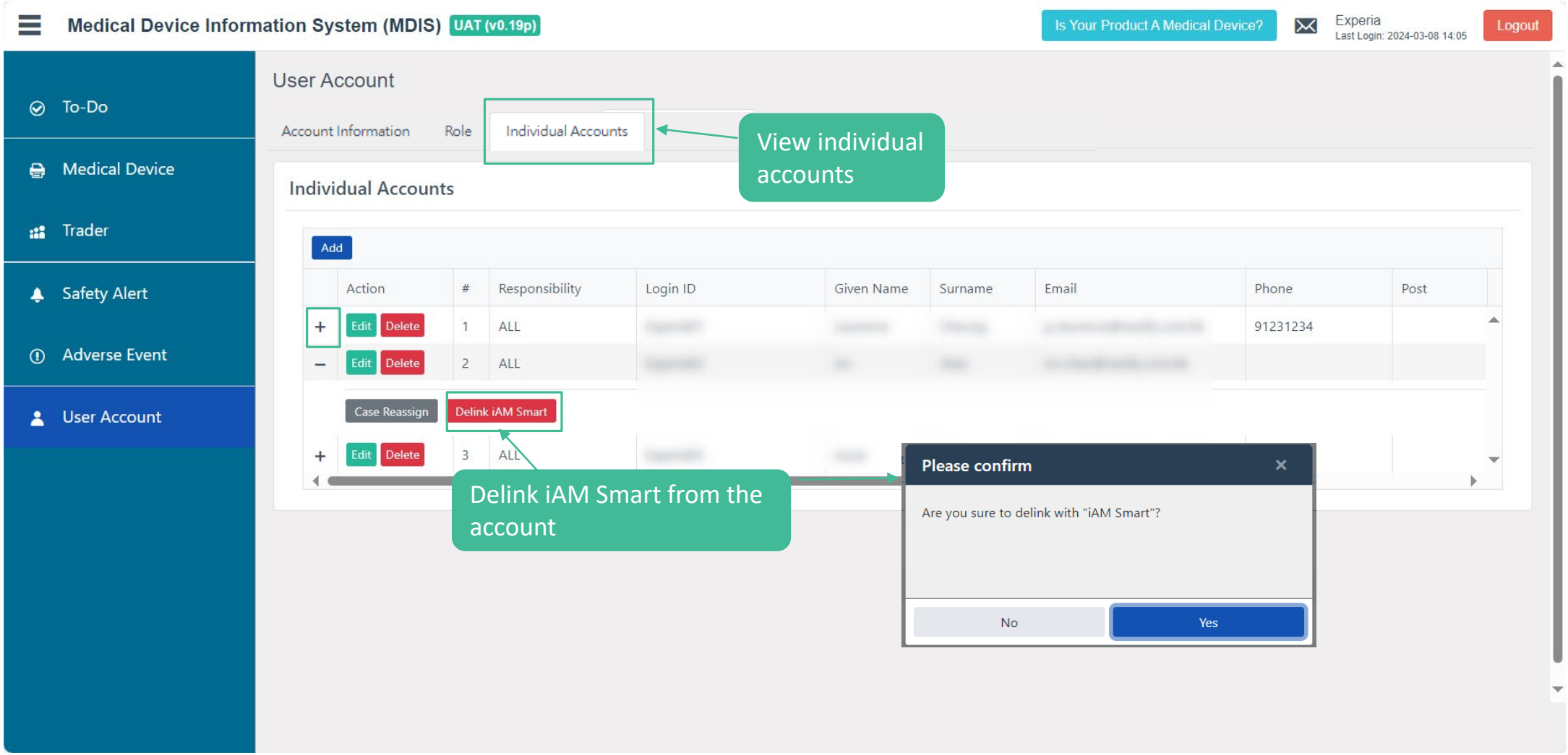
# Trader User – User Account Management – Edit account information (Cont.)



# Trader User – User Account Management – Delink iAM Smart



# 2) Functionalities in Individual User Interface

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# Functionalities in Individual User Interface

- General functions
  - User Account Management
  - To-Do Overview
  - Medical Device Overview / Searching
  - Trader Overview / Searching

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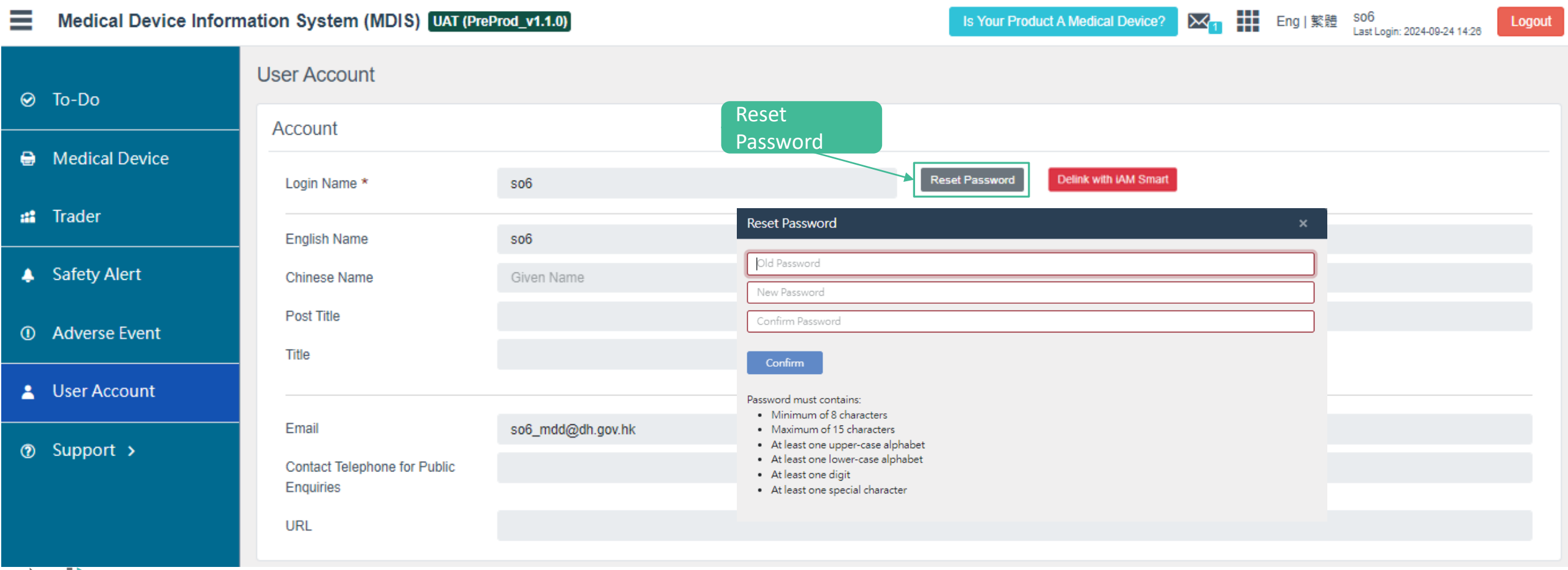
# Individual Users – User Account Management – reset Password

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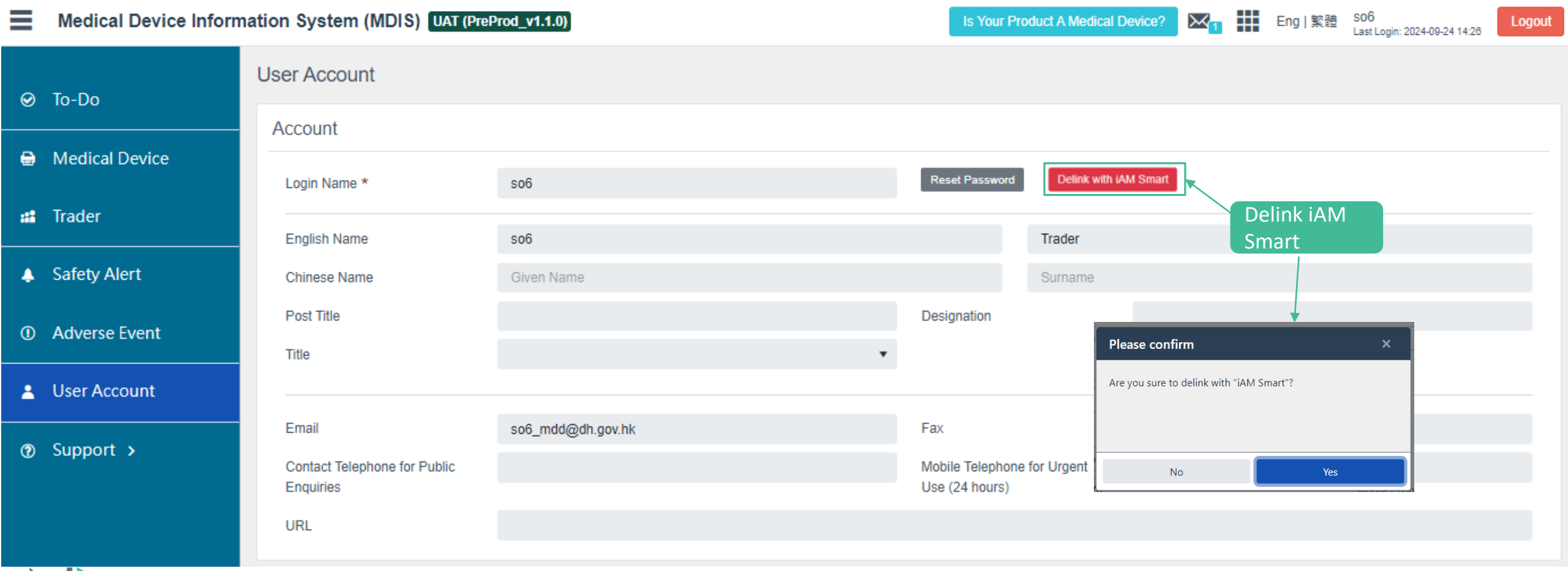
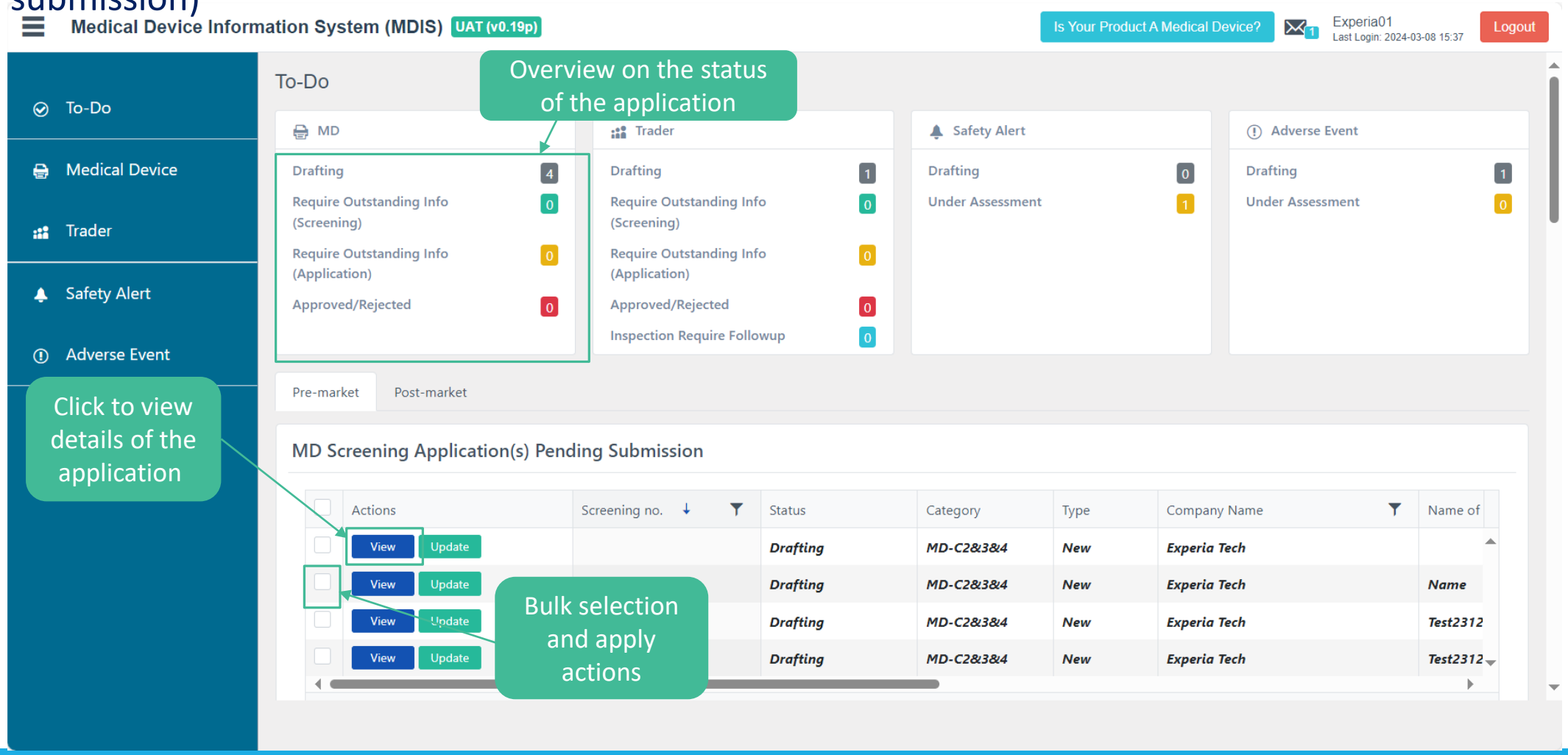
# Individual Users – User Account Management

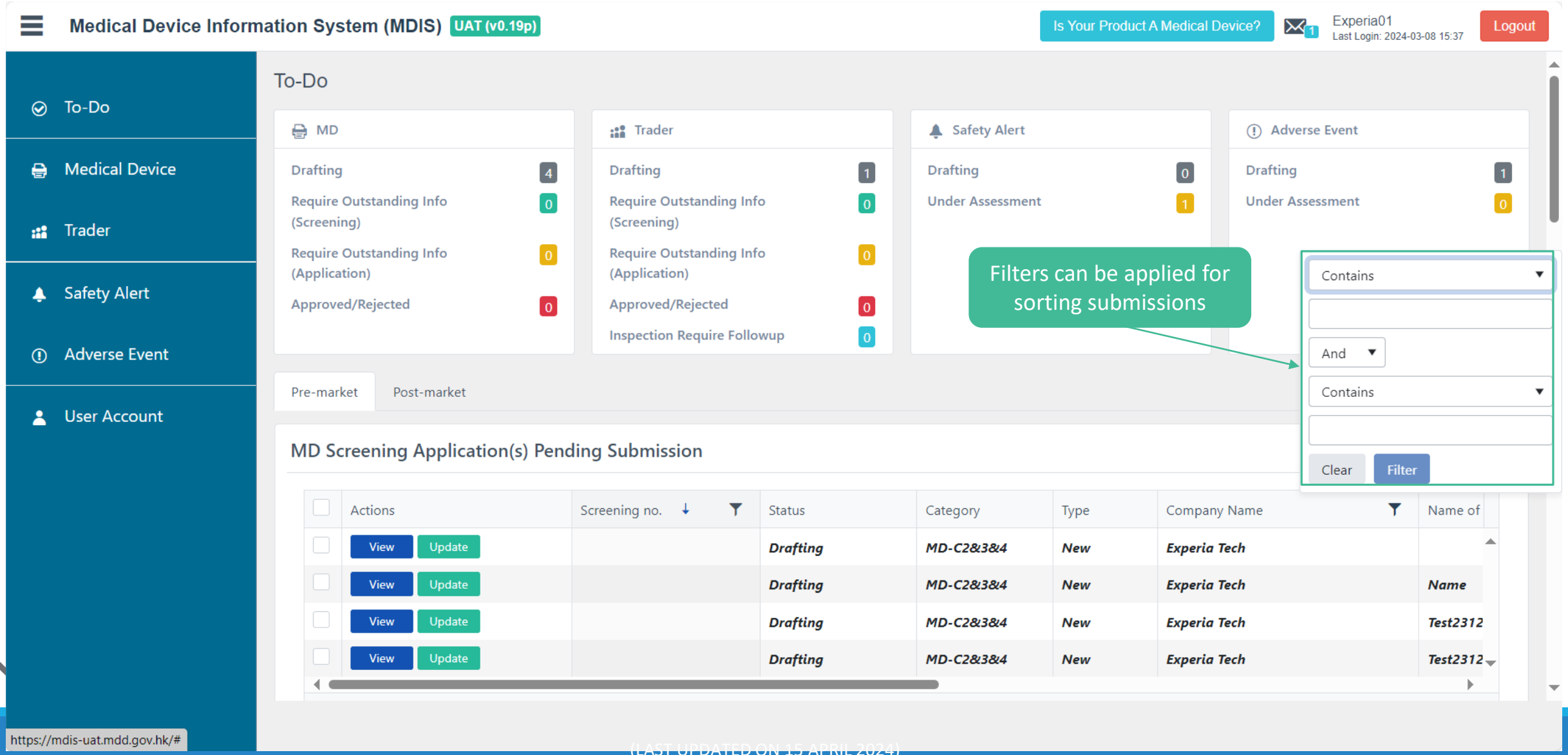


# Individual Users – To-Do Overview

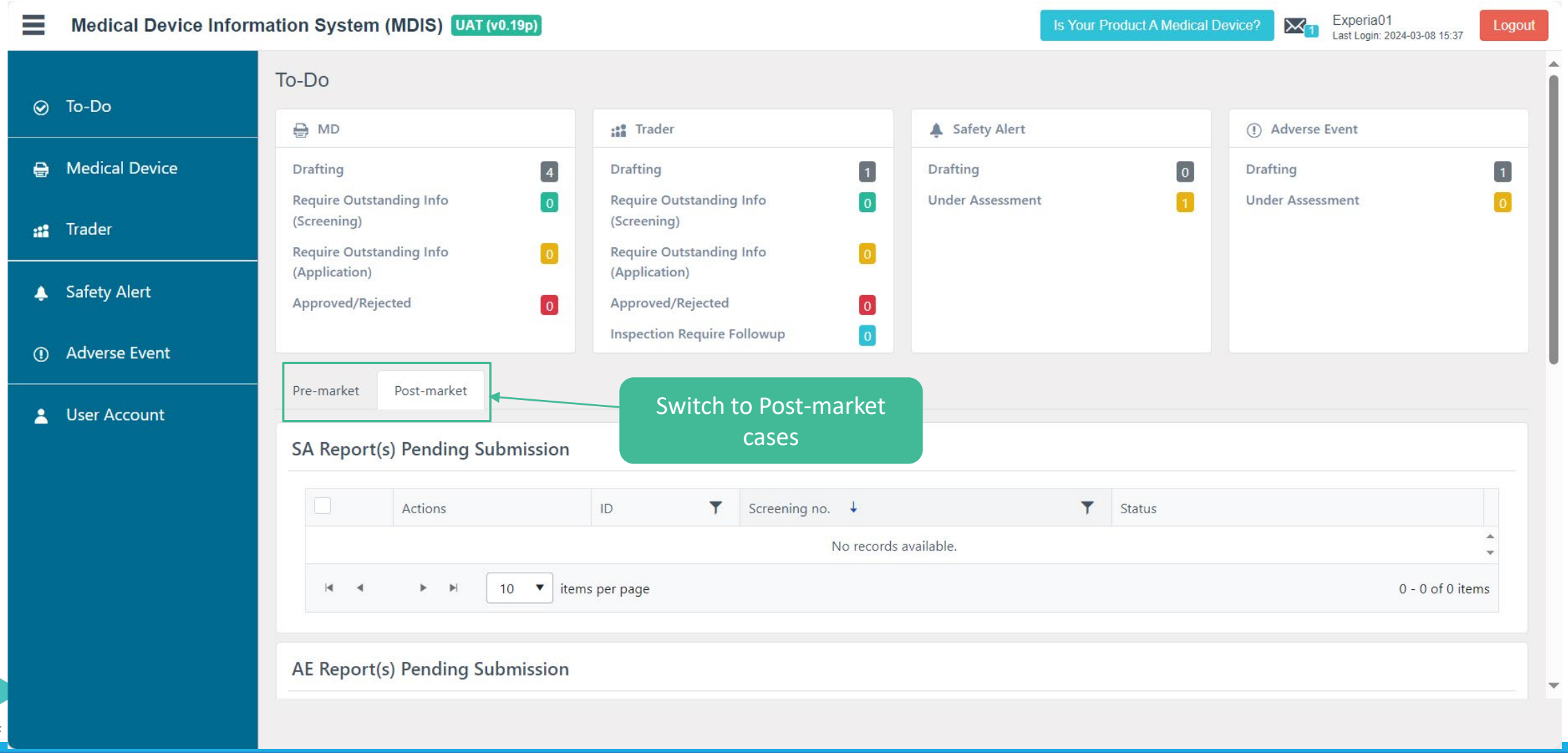
The To-Do list provides an overview of the tasks requiring further actions (e.g. pending for submission)



# Individual Users – To-Do Overview



# Individual Users – To-Do Overview



# 2) Functionalities in Individual User Interface
## -Report Medical Device Safety Alerts

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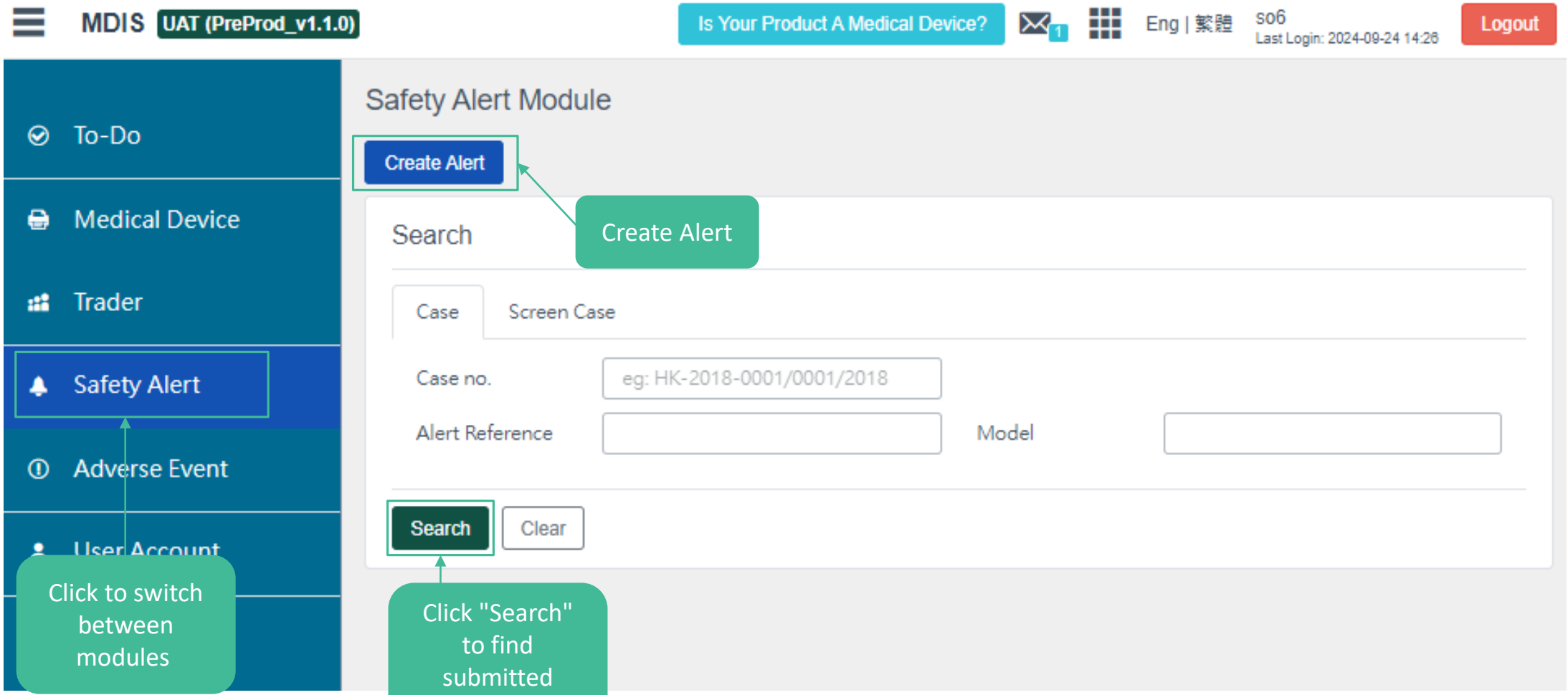
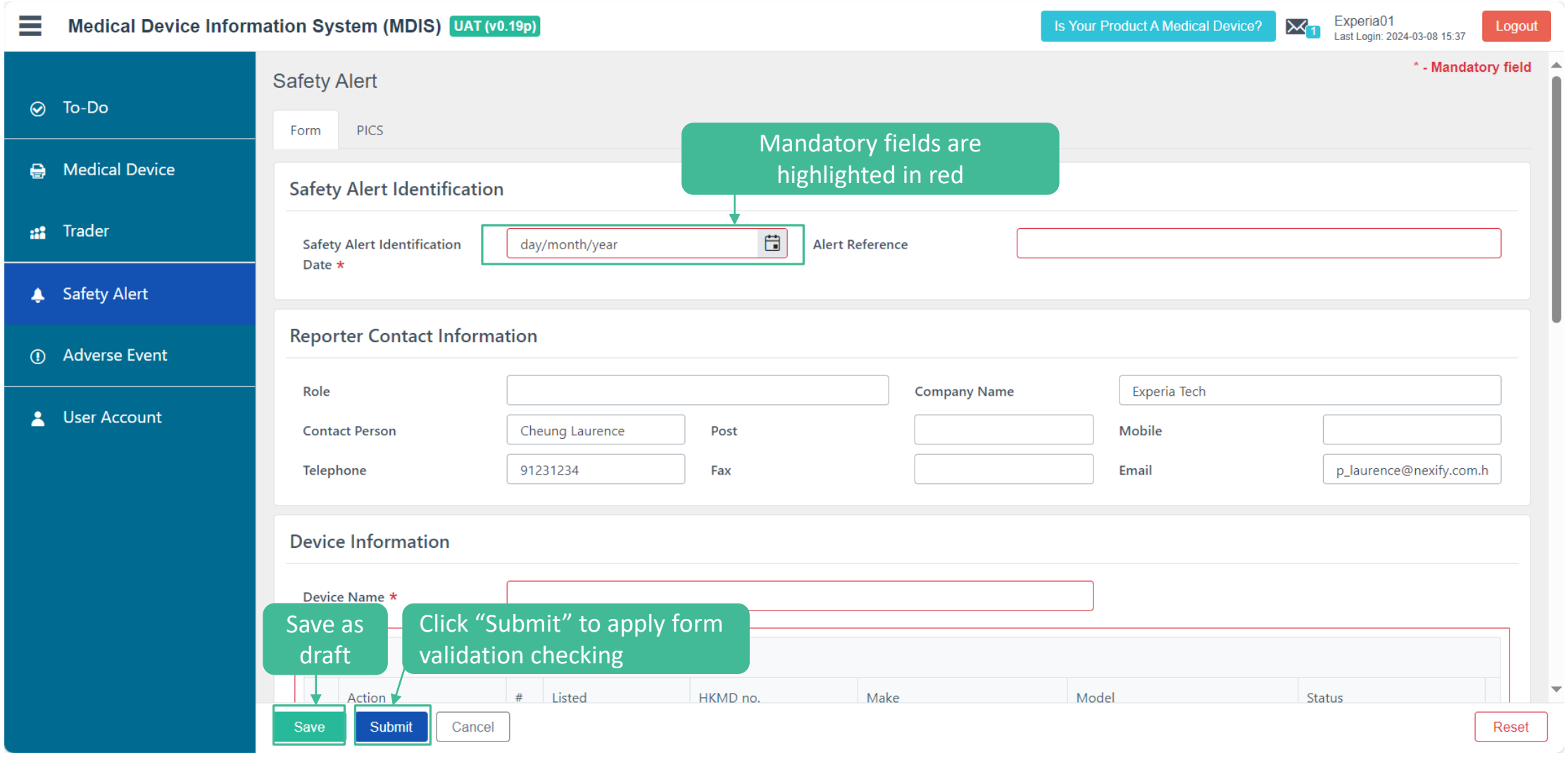
# Individual Users – Report Medical Device Safety Alert (P. 1-3)



# Individual Users – Report Medical Device Safety Alert (P. 2-3)



# Individual Users – Report Medical Device Safety Alert (P. 3-3)


A confirmation pop-up window will display the case number upon successful reporting.
*Example: Report sent <SA2024-S10250>*
The safety alert will be sent for MDD assessment.

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# 2) Functionalities in Individual User Interface
## -Report Medical Device Adverse Events

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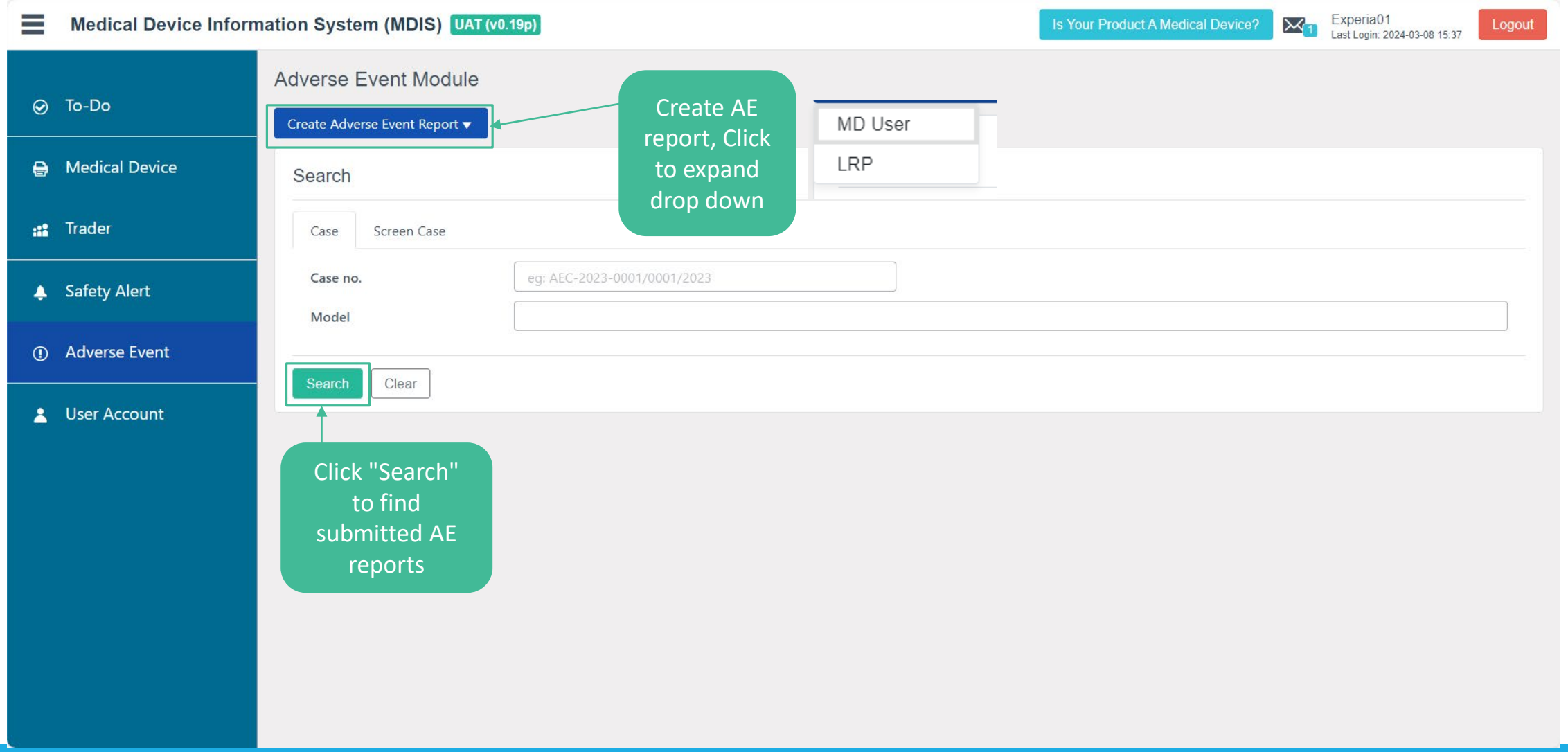
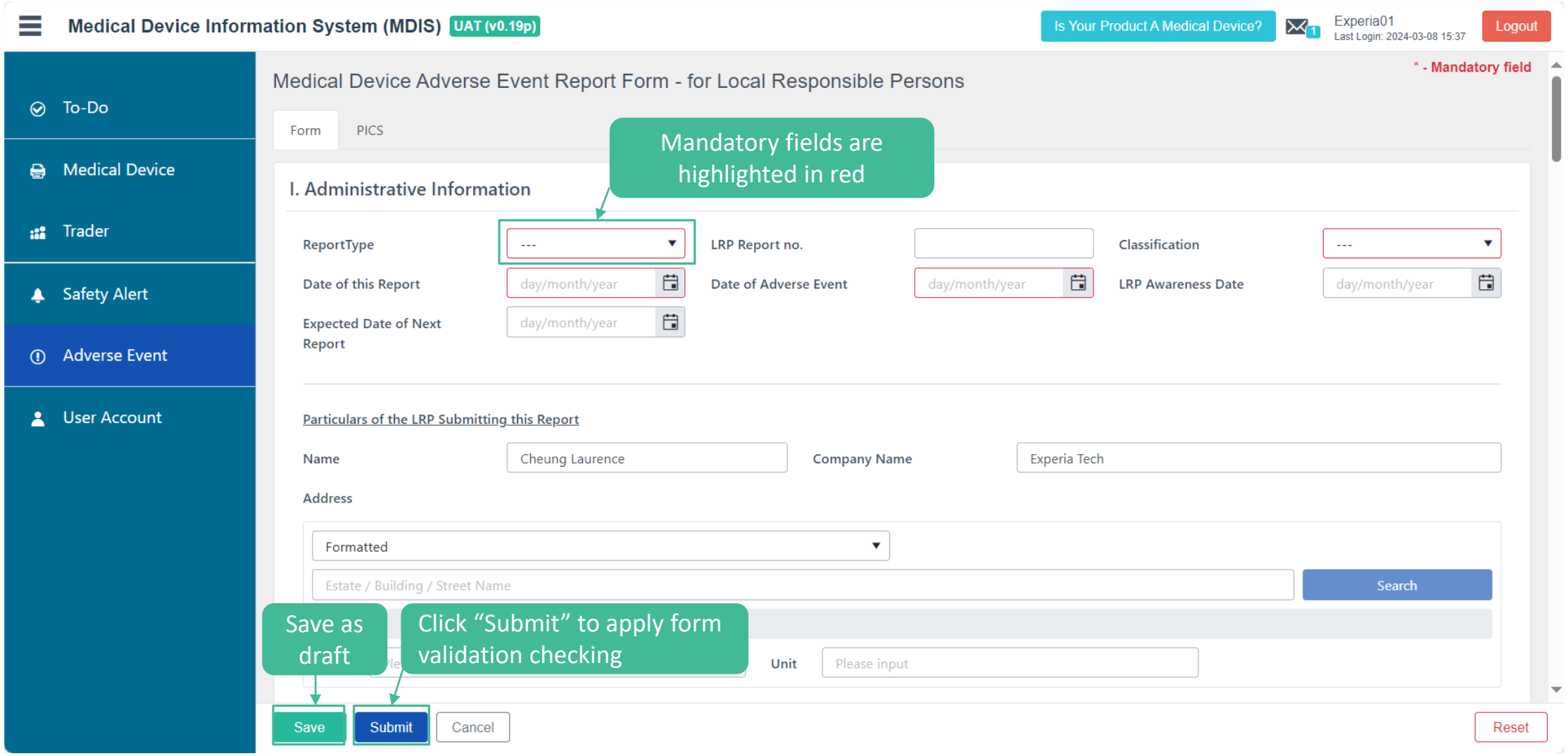
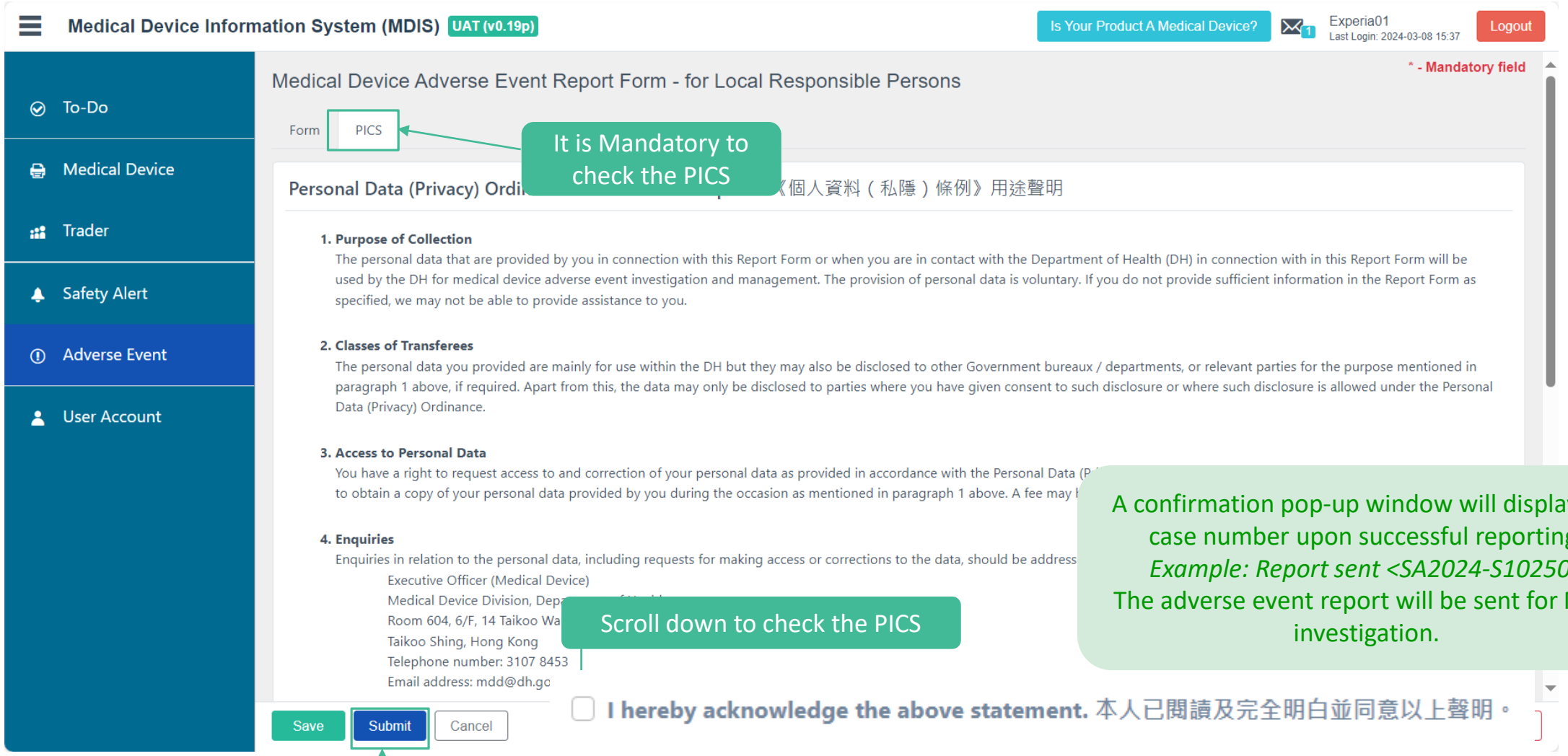
# Individual Users – Report Medical Device Adverse Event (P. 1-3)



# Individual Users – Report Medical Device Adverse Event (P. 2-3)



# Individual Users – Report Medical Device Adverse Event (P. 3-3)

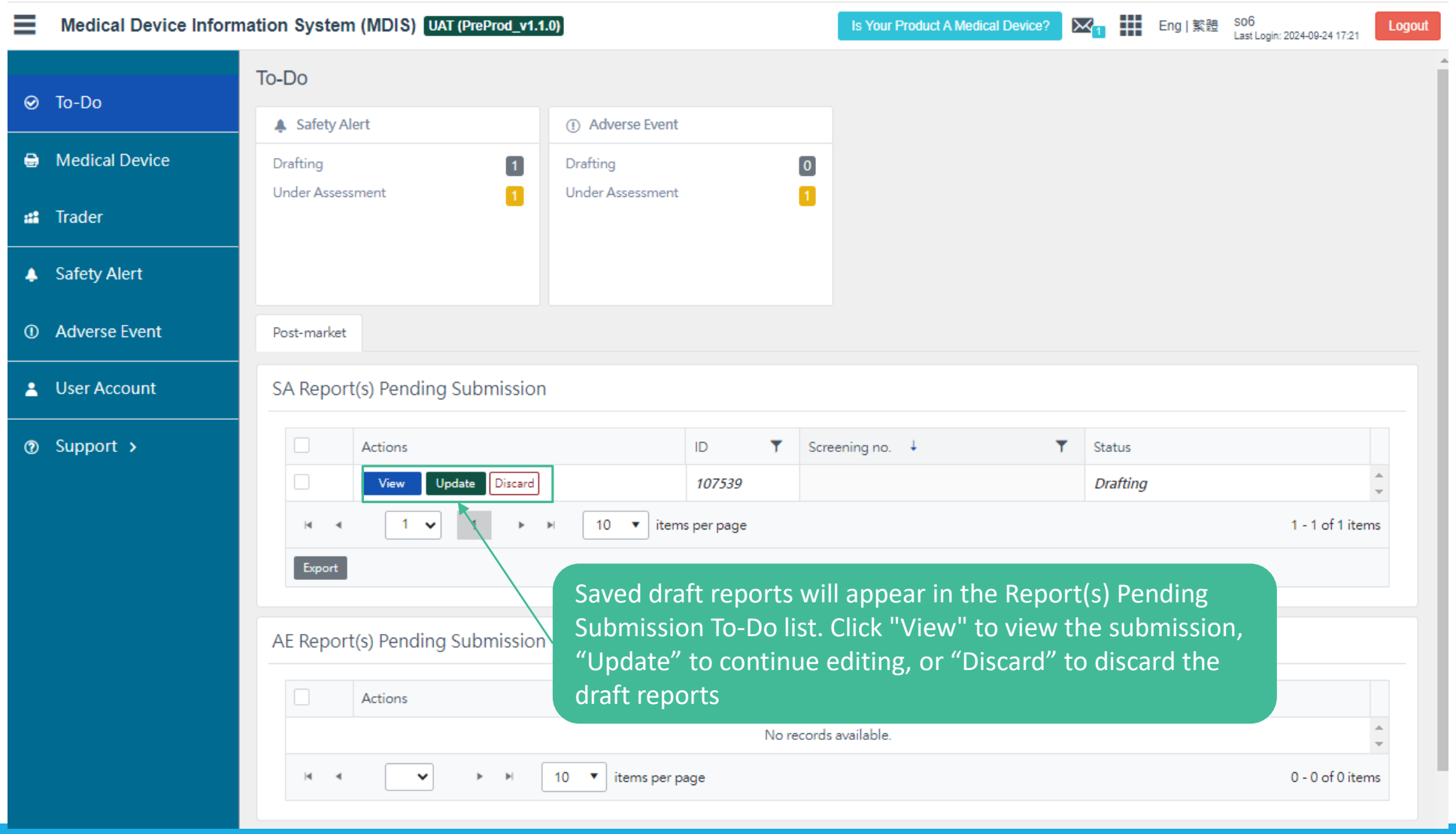



A confirmation pop-up window will display the case number upon successful reporting.
*Example: Report sent <SA2024-S10250>*
The adverse event report will be sent for MDD investigation.

# Functionalities in Individual User Interface

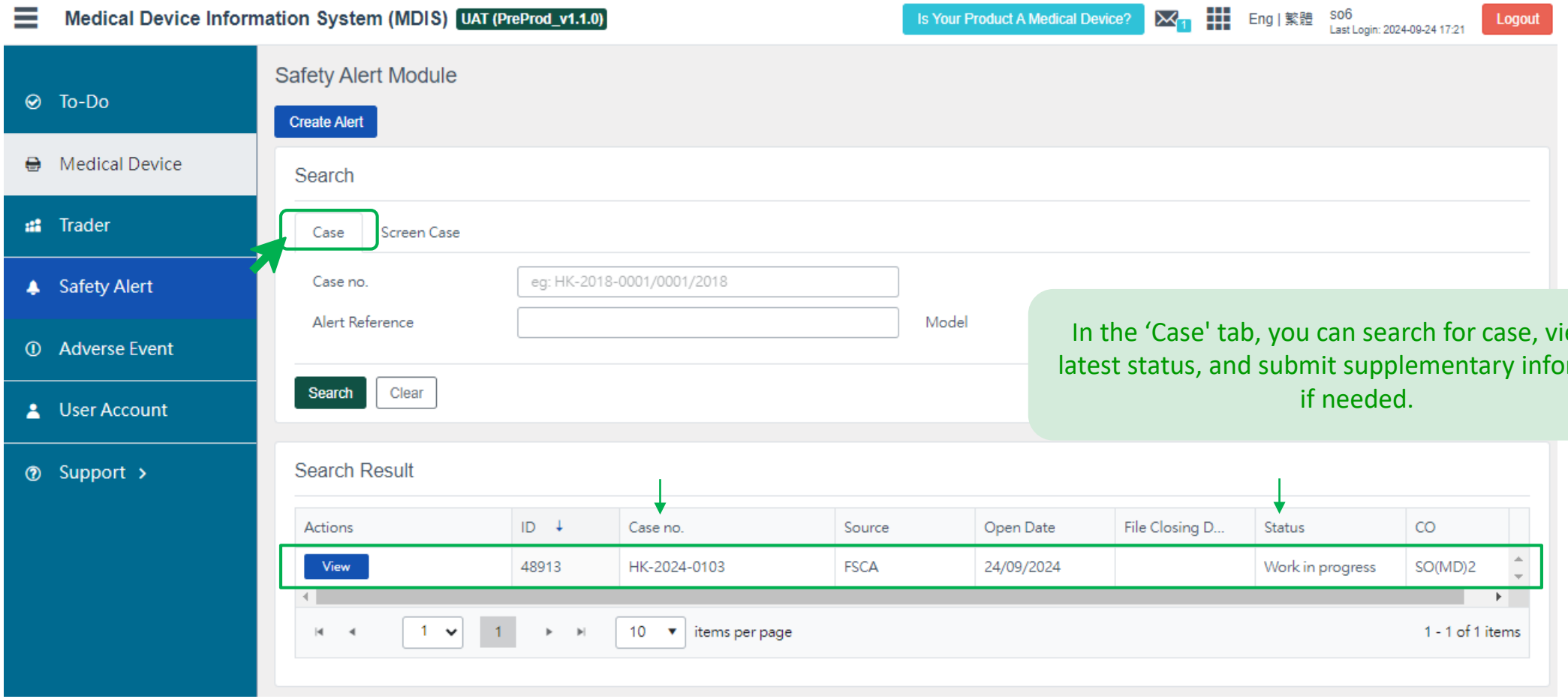
- Other reporting-related matters
  - Access draft reports
  - Checking report status
  - Responding to Case Enquiries

# Individual Users – Access draft Reports



# Individual Users – Check Report status

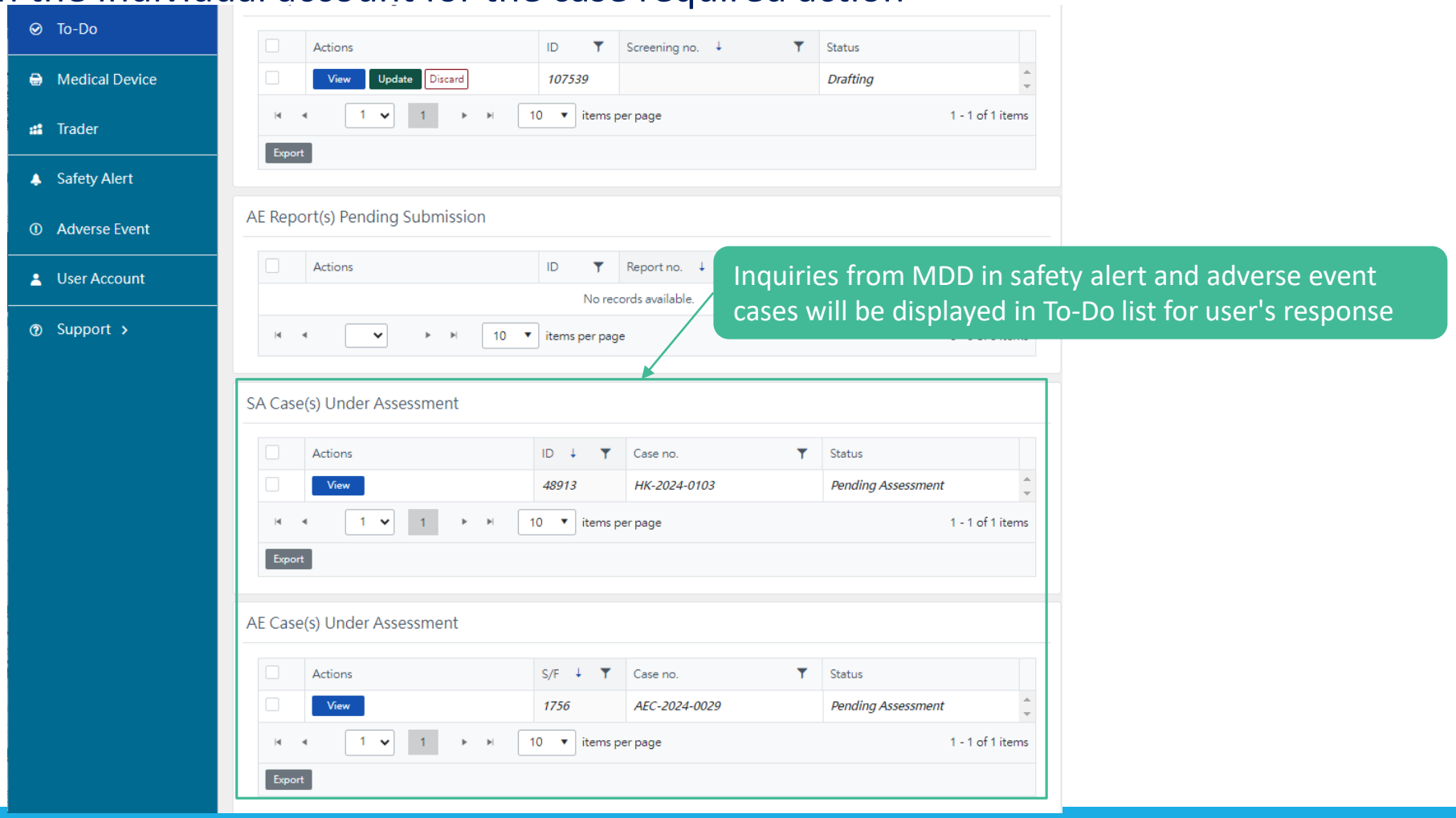
The status will be updated according to MDD's procedures. You can check the latest status by clicking “**Safety Alert**” / “**Adverse Event**” and search the case record of interest.




In the ‘Case' tab, you can search for case, view the latest status, and submit supplementary information if needed.

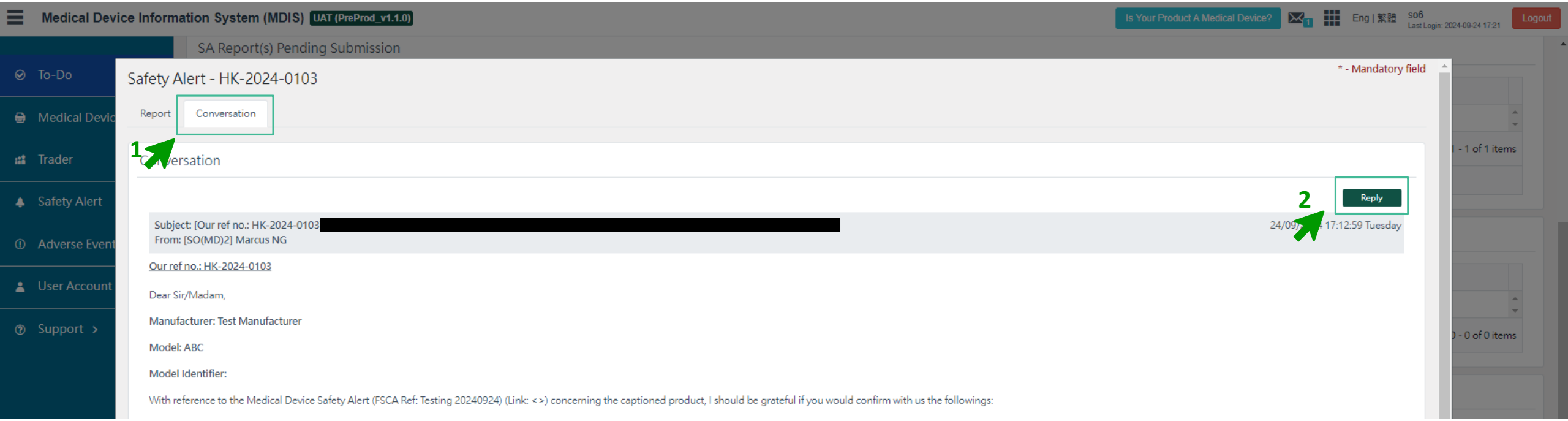
# Individual Users – Responding to Case Enquiries

After receiving notification email for new message from a particular case number, you can access the To-Do list in the Individual account for the case required action



# Individual Users – Responding to Case Enquiries

1. Access "**Conversation**" tab for the case to view the enquiry from MDD
2. Click "**Reply**" to provide complete reply or supplementary information



# Enquiry and Support

- Please reach out to our dedicated MDIS technical support team at 3702 5356 or email at mdis_support@nexify.com.hk whenever necessary.
- For other general enquiries related to applications under MDACS, please contact Medical Device Division at 3107 8484 or email at mdd@dh.gov.hk.

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