Protocol Assist Device Update and Tutorial

Lindsey Harris, Research Technician Associate
ESETT v1.3 Updates and Features

New features!

• Benzo check on Start Protocol screen
• PK/PD study reminder
• Fixed contact list
Updating Protocol Assist Device iOS

1. Settings > General > Software Update
2. “Install Now” and agree to Terms & Conditions
Updating ESETT App

1. Extras Folder > App Store > Updates > Purchased
2. Click “Update” box next to UVA ESETT app
Setting Up Study Drug Vial

Press ESETT icon

Vial needs scanned

Ready for enrollment

Protocol Assist Device
Touch the ESETT logo at the bottom of this screen to open the app.
Then touch the green button at the same time the infusion starts.

Set up Device
Enter or use the camera to scan the Web DCU and Vial Code.
Vial Code: Scan
Web DCU: Scan

Setup Device Continue Setup

Connection to service is active

Start Study for Drug ID 8015
Press to affirm eligibility and activate the 'Start Protocol' button
YES, patient is 2-17 years old
YES, last benz was at least 5 min ago
YES, last benz was less than 30 min ago
Press 'Start Protocol' at the same time that study drug infusion starts
Start Protocol
Change Setup Submit Logs
Setting up Study Drug Vial

- Scanning barcodes
  - WebDCU: Drug Tracking > Drug Receiving > Vial number
Setting up Study Drug Vial

**Set up Device**

Enter or use the camera to scan the Web DCU and Vial Code.

- **Vial Code:** 4937240...
- **Web DCU:** s493724...

**Setup Device**  **Continue Setup**

*Connection to service is active*

**Device Contacts**

Press to affirm eligibility and activate the 'Start Protocol' button:

- **YES, patient is 2-17 years old**
- **YES, last benzo was at least 5 min ago**
- **YES, last benzo was less than 30 min ago**

Press 'Start Protocol' at the same time that study drug infusion starts.

**Start Protocol**  **Change Setup**  **Submit Logs**

*Test SMS  Test EMail  Continue Setup*
Changing Vial Codes

- Press “Change Setup”
- Re-scan correct barcodes
PK/PD Acknowledgements

ESETT Trial

Time since start of infusion:

20:39

20 Minutes Acknowledgement
The first blood draw should take place between 20–50 minutes after start of study drug infusion.

Acknowledge

Second Blood Draw Reminder

The second blood draw should take place between 60–120 minutes after start of study drug infusion.

Connection to service is active
Unblinding

Reminder: Unblind by scanning vial barcode
Submitting Data

At this time, connect to Wi-Fi network if necessary.

- Treatment Protocol Complete
  - Please return device to use next box and give to ESETT study team
  - Complete Protocol

- Trial Results Ready
  - Make sure the device is on a reliable high-speed internet connection and click the Submit Results button to submit the results and reset the device.

- Connection failed. Reconnect to submit

- Submission not started

- Connection to service is active

- Trial Results Ready
  - Make sure the device is on a reliable high-speed internet connection and click the Submit Results button to submit the results and reset the device.

- Submission Complete
  - The submission completed successfully. The device should be ready to set up for the next trial.

- Ok

- Step 2 or 2 started. This might take awhile.

- Connection to service is active
Returning Use Next Boxes

• We’ll contact you to return boxes
• Those who’ve already returned boxes - thanks!
Resources

- Educational videos
  - ESETT > Study Team Only > Toolbox > Clinical Resources
- Protocol Assist Device User Manual
  - ESETT > Study Team Only > Manual of Procedures, sec 16.2

Or contact Lindsey Harris (liha@umich.edu) or Nia Bozeman (nbozeman@med.umich.edu) for assistance.