

Completing the Study Diary

Activating the device, the daily entry window, missed entries, corrections, syncing, and travel — for protocol VTX-1042-301

THE DIARY CANNOT BE BACKFILLED, AND THAT IS ON PURPOSE

An entry records how you felt on the day you made it. Once a day closes at midnight it stays closed. A missed day is recorded as missed — never estimated, never entered later, and never completed by anyone other than you.

PARTICIPANT ID VTX-1042-301-0142-0037	DEVICE Study-provided smartphone, asset 0142-DEV-0037	ACTIVATION CODE Mailed separately · expires 7 days after issue	DAILY ENTRY WINDOW 06:00 to 23:59 device local time
DAILY REMINDER 20:00 device local time	WEEKLY MODULE Sundays, open Sunday 00:00 to Monday 23:59	COMPLIANCE TARGET At least 80% of daily entries in each 4-week period	HELPDESK 1-888-555-0196, 24 hours

ACTIVATION — DO THIS AT THE DAY 1 VISIT OR WITHIN 7 DAYS

1. Power on the device and connect it to Wi-Fi. The diary will also work over the built-in cellular connection.

2. Open the VantaDiary app. It is the only app you need; the device is configured for the study and should not be used for anything else.

3. Enter the activation code from the letter mailed to you. The code expires 7 days after it is issued — if it has expired you will see ERR-217 and the coordinator will issue a new one.

4. Set a 6-digit PIN. Do not share it. Five wrong attempts locks the app with LOCK-3 and only the helpdesk can unlock it.

5. Confirm your participant ID appears on the home screen exactly as VTX-1042-301-0142-0037.

6. Complete the two practice entries with the coordinator so you have seen every screen before you go home.

7. Confirm the reminder time shows 20:00 and that the device volume is not muted.

If you prefer to use your own phone, ask the coordinator about the bring-your-own-device option. The same app, the same windows, and the same rules apply, and the site will verify the install before you leave.

WHAT THE DIARY ASKS, AND WHEN

MODULE	OPENS	CLOSES	ITEMS
Daily entry	06:00 each day	23:59 the same day	Symptom severity 0–10; morning stiffness in minutes; rescue medication taken yes or no and how many times; sleep disturbance 0–4
Weekly module	Sunday 00:00	Monday 23:59	Twelve-item activity impact questionnaire; one global impression of change item on a 7-point scale
Monthly item	First day of each study month	Last day of that month	A single satisfaction question
Visit-day prompt	Automatically on a scheduled visit date	End of that day	A reminder to bring the device and study drug to the visit

Answer for how you actually felt, not for how you think you should have felt. There is no right answer and nothing you record changes your care in the study.

THE DAILY ROUTINE

1. Any time after 06:00, open the app and enter your PIN.

2. Tap *Today's entry*. The date at the top must match today's date.

3. Answer all four items. The app will not submit a partial entry.

4. Review the summary screen, then tap *Submit*.

5. Wait for the green *Synced* badge. A grey *Saved offline* badge means the entry is stored on the device and will upload when you have a connection.

6. Close the app. The reminder at 20:00 stops once an entry is submitted.

An entry takes about 90 seconds. Most participants find it easiest to do it at the same time each day.

MISSED ENTRIES, CORRECTIONS, AND WHAT NEVER TO DO

SITUATION	WHAT ACTUALLY HAPPENS	WHAT YOU SHOULD DO	WHAT YOU MUST NOT DO
You forget a day	The day closes at 23:59 and is recorded as missed. Missing days is expected and does not put you out of the study.	Start again with the next day's entry and mention it at your next contact.	Do not try to enter it the next morning, and do not estimate what the day was like.
You realize an answer was wrong	A submitted entry cannot be edited. The record is locked as soon as it is submitted.	Call the coordinator at 555-0184. A data clarification is filed against the entry so the correct information is on record.	Do not submit a second entry for the same day to try to fix it.
You are away from the device	Entries made offline are stored on the device for up to 14 days and upload on the next connection.	Make the entry on time; connect the device within 72 hours.	Do not let the device stay offline past 14 days — stored entries can be lost.
Someone offers to fill it in for you	The diary is a record of your own experience and is attributed to you.	Complete every entry yourself. If you cannot, tell the coordinator.	Never let a family member, caregiver, or the study team complete an entry for you.
You have a side effect	The diary is not monitored in real time and no one at the site is alerted by what you enter.	Call the 24-hour study line at 555-0188 and also record it in the diary.	Do not report a side effect only in the diary.

DEVICE SYNC, CHARGING, AND CARE

- The app syncs automatically whenever it has a connection. You never have to sync manually.
- Connect the device to Wi-Fi or cellular at least once every 72 hours.
- Charge the device every night. A dead battery on a day you meant to answer counts as a missed entry.
- Do not factory reset, update the operating system, install other apps, or change the device date and time.
- If the device is lost, stolen, or damaged, call the helpdesk at 1-888-555-0196 within 1 business day. A replacement ships within 2 business days and your prior entries are already on the server.
- Return the device and its charger at the Week 52 visit.

TRAVEL AND TIME ZONES

- The diary uses the device's local time. Windows open and close on local time wherever you are.
- Crossing into a time zone more than 3 hours different can shorten or lengthen a single day's window. Tell the coordinator so the record reflects it.
- For international travel, notify the site at least 14 days in advance so roaming and study drug transport can be arranged.
- Never change the device clock manually. The app detects the change and raises ERR-441.
- Keep the device in your carry-on. Do not check it.
- Keep answering daily while you travel. Travel is not a reason to pause the diary.

TROUBLESHOOTING

CODE	WHAT YOU SEE	WHAT IT MEANS	WHAT TO DO
ERR-102	Unable to reach the server	No network connection. The entry is saved on the device.	Finish the entry anyway. Connect to Wi-Fi within 72 hours.
ERR-217	Activation code is no longer valid	The code expired 7 days after it was issued.	Call the coordinator at 555-0184 for a new code.
ERR-330	Sync conflict detected	The server already holds an entry for that date.	Do not re-enter. Call the helpdesk at 1-888-555-0196.
ERR-441	Device time does not match	The device clock was changed manually or drifted.	Do not adjust it yourself. Call the helpdesk; the entry is preserved.
LOCK-3	App locked after repeated PIN attempts	Five incorrect PIN entries.	Call the helpdesk at 1-888-555-0196 to unlock. Entries are not lost.
SYNC-OK	Green synced badge	The entry reached the server successfully.	Nothing. This is what you want to see.

HOW COMPLIANCE IS MEASURED — A WORKED SPECIMEN

STUDY WEEK	DAYS COMPLETED	DAYS IN THE WEEK	WEEKLY RATE
Week 1	7	7	100.0%
Week 2	6	7	85.7%
Week 3	7	7	100.0%
Week 4	5	7	71.4%
4-week period	25	28	89.3%

- The 4-week rate of 89.3% is above the 80% target, so the period passes.
- Week 4 on its own is 71.4%, below 80% for a 7-day period, so the coordinator will call to ask whether something is getting in the way.
- That call is a check-in, not a warning. Nothing about your participation changes because of a low week.
- Compliance is reviewed at every scheduled contact and shown to you on request.

Rates are the number of completed daily entries divided by the number of days in the period. Weekly and monthly modules are tracked separately and are not part of this calculation.

WHO TO CALL

IF YOUR QUESTION IS ABOUT...	CALL	NUMBER	WHEN
A side effect or anything urgent	24-hour study line	555-0188	Any time
The app, the device, an error code, or a lock	VantaDiary helpdesk	1-888-555-0196	24 hours
A missed entry, a correction, or travel plans	Naomi Ellsworth, CCRC, study coordinator	555-0184	Mon–Fri 8:00 a.m.–5:00 p.m.
Your rights as a research participant	Midland Central IRB	1-888-555-0191	Business hours

Consent boundary: Any video, animation, slide, handout, or plain-language summary prepared from this document — including the demonstration video this specimen was built for — **supplements the informed consent discussion and never replaces it.** No material of any kind replaces the

conversation with the study team or the signed, IRB-approved consent form. If a summary and the IRB-approved consent form disagree, the consent form controls.

Safety boundary: The diary records your experience. It is not monitored in real time, it does not alert anyone, and it is never a way to report a side effect, ask a medical question, or reach the study team. For anything urgent call 555-0188. For a life-threatening emergency call local emergency services first.

FICTIONAL SPECIMEN. Cedar Ridge Clinical Research Institute, Vantera Therapeutics, Midland Central IRB, protocol VTX-1042-301, the investigator, the coordinator, the participant identifier, the version and approval dates, the study drug, the reported frequencies, the reimbursement amounts, and every telephone number and address shown here are invented for demonstration only. This is not a real informed consent form, protocol, IRB-approved document, schedule of activities, or safety instruction, and nothing in it should be followed, signed, relied on, or reused as a template for a real study or a real participant.