EXACT e-Diary Certification Program

Evidera hereby certifies that _____ completed the
EXACT e-Diary Certification Program on this __ day of_____.

Name of Device: _____

Certification included the following elements:
- Evidera provided the vendor with a copy of the current screenshots in English
- Business Development EXACT training conducted (Review EXACT Background and Purpose)
- Technical EXACT training conducted (Review Screenshot Requirements, System Requirements for UAT Testing, and Additional Recommended Features)
- Vendor provided Evidera with screenshots of the EXACT and Evidera approved the screenshots based on:
    - Screenshot text is legible
    - Complete, correct EXACT text is included with instructions sentence, 14 items, and copyright statement
    - Screenshot text fits on screen with no breaks/gaps
    - Item and response options fit on 1 screen
    - Clear differentiation between response options
    - Screen titles: Question x of 14
    - Item and response options are left justified
    - Font size is consistent throughout the diary
- Vendor provided Evidera with system requirements for the EXACT and Evidera approved the requirements based on:
    - Patient bedtime can be entered and updated as needed
    - Diary entry begins on the same day of setting bedtime
    - Completion window around patient bedtime (recommend $\pm$ 3 hours)
    - Diary is available to patient during specified window
    - Diary is not accessible to patient outside of specified window
    - Message indicating when the patient is out of the window to complete diary.
    - Diary can be completed only once for each (study) day
    - Message indicating diary has already been completed or diary not available
    - Diary begun just prior to completion window closeout can complete that day's entry
    - An alarm before bedtime (recommend 1 hour)
    - An alarm at bedtime if diary not completed yet
    - An alarm post-bedtime if diary not completed yet (recommend 1 hour)
    - Welcome screen appears at diary activation
    - Patient-specific Access Code (PIN) required to access diary
    - Only specified number of password or pin code characters accepted
    - Only specified characters accepted (i.e. numerals, alphabet)
    - Instruction sentence is included at beginning of diary
    - Complete, correct text of the EXACT is included
    - Correct Copyright screen is included
    - One item per screen
    - Response options present on the same screen as the item

- o Smooth transitions between items
  - o Selecting "Next" or equivalent command moves to the next question sequentially
  - o Selecting "Back" or equivalent command returns to the previous question
  - o Skipping questions is not permitted
  - o Pop-up message or sound indicating a question cannot be skipped
  - o Only one response per question is allowed
  - o Selected response option is visibly selected via radio button, highlighting, etc.
  - o Selected responses saved as patient moves through the diary
  - o Response options can be changed prior to saving or exiting diary.
  - o Selected answers for the entire diary can be reviewed
  - o Selecting "Exit" or equivalent command allows participant to exit diary
  - o Screen idle time after X minutes, returns to log-in window or welcome screen (patient may resume questionnaire where they left off after logging in if time out window has not expired)
  - o Device time out after X minutes, returns to log-in window or welcome screen (partial completion not saved, patient must start over from beginning)
  - o Patient data for partial, or incomplete diary entries will not be saved and the entire diary will need to be completed again upon re-accessing the diary
  - o Daily compliance is tracked and appears at end of diary
  - o Battery power indicator visible
  - o Diary entries not accessible once saved
  - o Patient transmits data (daily preferred)
- User Acceptance Testing (UAT) conducted by Evidera and all of the above confirmed

Exceptions:

Comments:
_____
_____
_____

Signature:_____Date:_____
Evidera

Disclaimer: Completion of EXACT eDiary certification program signifies that Evidera has reviewed and approved the above components, except where specifically noted. Device selection and use are the sole responsibility of the EXACT user.   Programming and device-related functionality are the sole responsibility of the eDiary vendor. Evidera, together with its affiliates and its and their directors, officers, employees and agents expressly disclaims any and all liability as to any study outcomes or results obtained, or liability arising from any use of the EXACT or reliance on such information or information provided herein.