



## Considerations for Selecting a Device for Electronic Daily Diary Administration

The following is a list of suggested criteria for sponsors to take into consideration when choosing a device for daily diary administration in their trials, particularly those lasting a prolonged period of time, such as 6 months to a year.

Criteria	Aspects to Consider
<i>Physical features</i>	
<b>Device size</b>	Larger devices may be less portable. Smaller devices may be more difficult to handle and use.
<b>Screen size</b>	For the EXACT, screen sizes smaller than 2.75 in x 1.5 in may not be sufficient to display each question and responses on the same screen. Smaller screens provide less real estate to display text and may be problematic for longer questions and responses. Consider the impact of translations which may run 25% longer than the English source. Modification of existing translations to fit screen size is not permitted.
<b>Font size</b>	Consider the age of your target population; Font should be large enough to be easily readable. Will fonts have to be reduced to accommodate translations?
<b>Font resolution</b>	The clearer and sharper the font, the easier it is to read when smaller. Large fonts that are not sharp can be more difficult to read than smaller clearer fonts.
<b>Response area or buttons</b>	Consider how large the response area is. If the response area is too small, patients may have difficulty getting their responses to register which could cause frustration and lower compliance. Large enough to be selected without choosing the wrong answer. Consider how much pressure must be applied to a response area for the device to register a selection.
<i>Navigation</i>	How easy is it to move from screen to screen? Is it intuitive?
<b>Changing responses</b>	How easy is it to change an answer when completing the diary?
<b>Data transmission</b>	Does data transmission take place at the clinical site or is it transmitted by the patients?



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	<p>Is transmission wireless or analog?</p> <p>Is the device capable of automatic transmission to the central server?</p> <p>If patients are required to upload data nightly and the transmission requires additional hardware, this could cause frustration and lower compliance.</p> <p>Do you need immediate access to the data? Access within one day? One week? Monthly?</p> <p>How closely will the patients be monitored for compliance by sites, i.e., do they need to view data daily or will data uploads at scheduled clinic visits suffice?</p>
<i>Usability</i>	
<b>Completion time</b>	<p>How long does it take to answer a question and move to the next screen? The more clicks or taps needed, the more frustrated the patient may become when answering over a long period of time, resulting in reduced compliance.</p>
<b>Touchscreen</b>	<p>Can answers be selected by touching the screen and is using one's finger possible as well as a stylus?</p> <p>Consider older populations or those with conditions like arthritis for whom holding a stylus may be more difficult than tapping with a finger.</p>
<b>Ease of use</b>	<p>Is the device easy to use for patients who are not technology savvy? If difficult to use, compliance may decrease.</p> <p>Consider older populations or those with conditions like arthritis for whom pressing buttons may be more difficult than using a touchscreen.</p> <p>Consider whether the device can be laid flat on a table and continue to be legible so that patients who do have trouble holding a device steady can still answer the questions using a touchscreen or buttons.</p>
<b>Integrated device</b>	<p>If using a device that integrates a diary with other functionality but sacrifices usability, is the extra functionality truly necessary for your study?</p>
<i>Other considerations</i>	



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<b>Compliance program</b>	<p>Does the vendor have processes to enhance compliance, such as reminder alarms, positive reinforcement messages on the device, patient take-home instructions, and an available help desk?</p> <p>Consider whether the vendor can tailor compliance features like alarms and diary completion windows to be patient-specific (alarms 1 hour prior to bedtime, at bedtime, 1 hour post bedtime; study window <math>\pm</math> 3 hours from bedtime), or if the alarms and/or diary will follow 1 study-wide guideline (i.e. alarm goes off at 8PM every evening regardless of bedtime; study completion window 3PM-3AM).</p>
<b>Web portal</b>	<p>How easy is it for the sites to view patient data and for study monitors to view overall site compliance data?</p>