



## 1.4.4 Frequently Used Terms

The following table displays terms that are frequently used within OpenClinica.

Term	Definition
<b>Study</b>	A study is a collection of <b>events</b> and <b>forms</b> that contain participant data.
<b>Participant</b>	<p>A participant (sometimes referred to as a <i>subject</i>) is a person who provides data for the study.</p> <ul style="list-style-type: none"><li>• If the <b>Participate</b> module is activated, participants can enter data themselves.</li><li>• If the <b>Randomize</b> module is activated, participants can be randomly assigned to groups (e.g., placebo or treatment) without bias from demographics such as age, sex, or gender.</li></ul>
<b>Event</b>	<p>An event is a collection of one or more <b>forms</b>. Events can be:</p> <ul style="list-style-type: none"><li>• <b>Visit-based, non-repeating</b>: A scheduled occurrence (e.g., <i>Baseline</i>)</li><li>• <b>Visit-based, repeating</b>: A repeatable scheduled or unscheduled occurrence (e.g., <i>Cycles in Oncology trials, Unscheduled Visits</i>)</li><li>• <b>Common, repeating</b>: An unscheduled but repeatable occurrence (e.g., <i>Adverse Event</i>)</li><li>• <b>Common, non-repeating</b>: An unscheduled, one-time occurrence (e.g., <i>Termination</i>)</li></ul>
<b>Form</b>	<p>A form (or CRF) is an electronic record of participant data that can include:</p> <ul style="list-style-type: none"><li>• <b>Items</b> - individual data fields (e.g., blood pressure, date of visit).</li><li>• <b>Constraints</b> - rules that define acceptable input values (e.g., numeric ranges, required fields).</li><li>• <b>Relevance logic</b> - conditional rules that show or hide fields based on prior responses.</li><li>• <b>Calculations</b> - auto-derived values (e.g., BMI from height and weight).</li><li>• <b>Metadata</b> - labels, instructions, and coding standards to ensure consistent data entry.</li></ul> <p>Users with the appropriate level of form access can enter data into a Form.</p> <ul style="list-style-type: none"><li>• If the <b>Participate</b> module is activated, a form can be published as a <i>Participate Form</i>, allowing participants to enter data from their own devices.</li><li>• If the <b>Consent</b> module is activated, a form can be published as an <i>eConsent Form</i>, allowing participants to provide consent in a manner compliant with <b>21 CFR Part 11</b>.</li></ul>
<b>Study Designer</b>	<p>Study Designer is the interface where Data Managers create Events and Forms.</p>
<b>Study Runner</b>	<p>Study Runner is the interface where users enter data into the study in either <b>Test</b> or <b>Production</b> environments. Depending on your access level, you may be able to:</p> <ul style="list-style-type: none"><li>• Manage participants / events</li><li>• View/enter data</li><li>• Create, update or close queries</li><li>• Perform Source Data Verification (SDV)</li><li>• Import data</li><li>• Extract data</li></ul>

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