

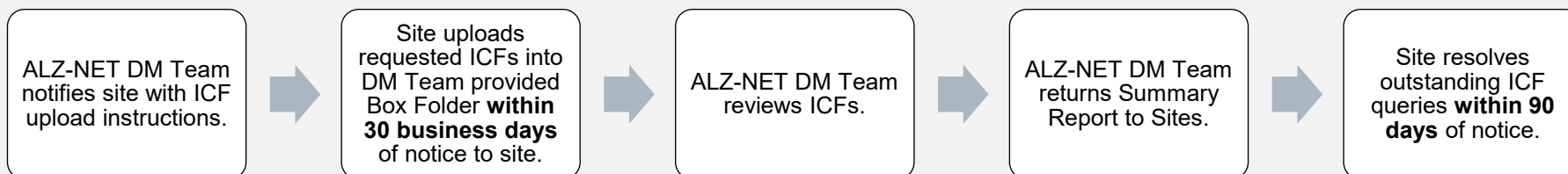


### Overview

This document summarizes the ALZ-NET Data Quality Management Program key elements outlined in the [ALZ-NET Data Quality Management Policy](#).

### Informed Consent Form (ICF) Review

**What to Expect:** To ensure ICF completeness and accuracy, four (4) randomly selected ICFs will be selected for review by the ALZ-NET Data Management (DM) Team after the site's 10<sup>th</sup> patient enrollment and every 50 enrollments thereafter (e.g. 50, 100, etc.).



### Quarterly Data Compliance Assessment

**What to Expect:** Each quarter, the ALZ-NET DM Team will complete an assessment of a site's compliance with data submission timelines and query responsiveness. The assessment will result in a color-categorization. Review your compliance score on your monthly site data reports or contact [alznet-data@acr.org](mailto:alznet-data@acr.org) for a status update.

Compliant	Warning	Non-Compliant
<p>≤20% overdue forms &amp; ≤25% open queries</p> <ul style="list-style-type: none"><li>• <b>No immediate action required.</b></li><li>• Site compliance status assessed at next quarterly interval.</li></ul>	<p>Between 21-49% overdue forms <b>OR</b> Between 26-49% open queries</p> <ul style="list-style-type: none"><li>• Site instructed to <b>resolve outstanding data queries AND overdue forms before</b> next quarterly report.</li><li>• <b>Check-in call recommended</b> but not required.</li><li>• <b>Failure to comply</b> advances site to non-compliant status.</li></ul>	<p>≥50% overdue forms &amp; ≥50% open queries</p> <ul style="list-style-type: none"><li>• <b>Site required to complete a check-in call</b> with DM Team to review data and complete a refresher training.</li><li>• <b>Site has 90 days to improve compliance status</b> or shows significant progress in resolving data.</li><li>• <b>Site required to submit CAPA</b> via DocuSign template if progress is not made after 90 days.</li><li>• <b>Site may be subject to enrollment suspension or termination</b> if progress is not made after 3 quarterly reporting cycles.</li></ul>