

1. [ADaM Home on the CDISC Portal](#) (Warning - the portal is being removed and documents are being transferred to the wiki)
2. [ADaM Home on the CDISC Wiki](#) (Access may be restricted to ADaM Team Members)

<p><b><u>Leadership Team (ALT)</u></b></p> <ul style="list-style-type: none"> <li>• Tatiana Sotingco - Current Lead</li> <li>• Sandra Minjoe - Former Lead</li> <li>• Brian Harris - Future Lead</li> </ul>
<p><b><u>Leadership Mentors</u></b></p> <ul style="list-style-type: none"> <li>• Deborah Bauer</li> <li>• Susan Kenny</li> <li>• Nate Freimark</li> <li>• Jack Shostak</li> <li>• John Troxell</li> <li>• Steve Wilson</li> </ul>

<p><b><u>Team Mission</u></b></p> <p>To provide metadata models and examples of analysis datasets used to generate the statistical results for a regulatory submission and other analysis needs.</p>
<p><b><u>Scope</u></b></p> <p>The ADaM Team develops standards for the submission of analysis datasets that support the creation of statistical summaries for clinical trials. The Analysis Data Model (ADaM) assumes that analysis datasets are created primarily from source data compliant with the Study Data Tabulation Model (SDTM). The ADaM is described by three primary documents: the Analysis Data Model (<b><i>Model Document</i></b>), its Implementation Guide (<b><i>ADaMIG</i></b>), and the Occurrence Data Structure (<b><i>OCCDS</i></b>) document. There are other supportive documents such as ADaM Basic Data Structure (BDS) for Time-to-Event (TTE) Analyses and Analysis Results Metadata (ARM).</p> <p>Throughout the ADaM documents, it is acknowledged that clinical trials are unique, and that the design of analysis datasets is driven by the scientific and medical objectives of the study. Clear communication regarding the analyses which support these objectives is a foundational principle.</p> <p>The ADaM team continues to support and enhance our documents, supports the data standardization needs from regulatory agencies and therapeutic-area focused initiatives.</p>

<p><b><u>Stakeholders/Constituency</u></b></p> <ul style="list-style-type: none"> <li>• Regulatory Authorities</li> <li>• Standards Development Organizations</li> <li>• Pharmaceutical, Biologic, Medical Device, and Diagnostic Sponsors</li> <li>• Contract Research Organizations</li> <li>• Consultants</li> </ul>
<p><b><u>Collaborations</u></b></p> <p>The ADaM Team works closely with other CDISC Teams, who utilize or leverage the ADaM standard to develop their own IG, including:</p> <ul style="list-style-type: none"> <li>• SDS (SDTM)</li> <li>• Devices</li> <li>• Define-XML</li> <li>• SHARE</li> <li>• TA Project Teams</li> </ul> <p>The ADaM team also participates in PhUSE initiatives</p>
<p><b><u>Operating Model &amp; Meetings</u></b></p> <ul style="list-style-type: none"> <li>• Full team meets every other week on Monday 1:00-2:30 pm US Pacific time</li> <li>• Sub-teams set own meeting schedule</li> <li>• Sub-team leads meet monthly as needed</li> <li>• ALT + Mentors meet weekly as needed</li> </ul>