

<b>General Information</b>	
<b>YODA Project (Protocol) ID:</b>	2025-0008
<b>Date Proposal Received by YODA Project:</b>	8-Jan-2025
<b>Product Name(s):</b>	DARZALEX (Daratumumab)
<b>Condition(s) Studied:</b>	Multiple Myeloma
<b>NCT Number(s), Protocol Number(s) and Title(s):</b>	<ol style="list-style-type: none"> <li>1. NCT02076009 - 54767414MMY3003 Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects With Relapsed or Refractory Multiple Myeloma</li>   <li>2. NCT02136134 - 54767414MMY3004 Phase 3 Study Comparing Daratumumab, Bortezomib and Dexamethasone (DVd) vs Bortezomib and Dexamethasone (Vd) in Subjects With Relapsed or Refractory Multiple Myeloma</li>   <li>3. NCT01985126 - 54767414MMY2002 An Open-label, Multicenter, Phase 2 Trial Investigating the Efficacy and Safety of Daratumumab in Subjects With Multiple Myeloma Who Have Received at Least 3 Prior Lines of Therapy (Including a Proteasome Inhibitor and IMiD) or Are Double Refractory to a Proteasome Inhibitor and an IMiD</li>   <li>4. NCT02252172 - 54767414MMY3008 A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects With Previously Untreated Multiple Myeloma Who Are Ineligible for High Dose Therapy</li>   <li>5. NCT03180736 - 54767414MMY3013 A Phase 3 Study Comparing Pomalidomide and Dexamethasone With or Without Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma Who Have Received at Least One Prior Line of Therapy With Both Lenalidomide and a Proteasome Inhibitor</li>   <li>6. NCT02195479 - 54767414MMY3007 A Phase 3, Randomized, Controlled, Open-label Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination With VMP (D-VMP), in Subjects With Previously Untreated Multiple Myeloma Who Are Ineligible for High-dose Therapy</li> </ol>

**Data Sharing Request Due Diligence Assessment**

	<p>7. NCT03277105 - 54767414MMY3012 A Phase 3 Randomized, Multicenter Study of Subcutaneous vs. Intravenous Administration of Daratumumab in Subjects With Relapsed or Refractory Multiple Myeloma</p> <p>8. NCT03412565 - 54767414MMY2040 A Multicenter Phase 2 Study to Evaluate Subcutaneous Daratumumab in Combination With Standard Multiple Myeloma Treatment Regimens</p> <p>9. NCT01615029 - 54767414GEN503 An Open Label, International, Multicenter, Dose Escalating Phase I/II Trial Investigating the Safety of Daratumumab in Combination With Lenalidomide and Dexamethasone in Patients With Relapsed or Relapsed and Refractory Multiple Myeloma</p> <p>10. NCT02874742 - 54767414MMY2004 Study Comparing Daratumumab, Lenalidomide, Bortezomib, and Dexamethasone (D-RVd) Versus Lenalidomide, Bortezomib, and Dexamethasone (RVd) in Subjects With Newly Diagnosed Multiple Myeloma</p> <p>11. NCT02951819 - 54767414MMY2012 Daratumumab Plus Cyclophosphamide, Bortezomib and Dexamethasone (Dara-CyBorD) in Previously Untreated and Relapsed Subjects With Multiple Myeloma</p>
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**Proposal Review**

<p>Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. <b>Is there any reason why the study/studies listed should no longer be shared?</b></p>	No
Comments if 'Yes':	
<p>Question 2: On review of the proposal, is there any data that has been requested that may be missing from the clinical database?</p>	No
Comments if 'Yes':	
<p>Question 3: Is a similar analysis underway, or completed and pending disclosure by J&amp;J?</p>	Yes
Comments if 'Yes':	