

**MRCT CENTER- Wellcome Trust Meeting on  
The Future of Clinical Trial Data Sharing**

**Location:** Wellcome Trust, Gibbs Building; 215 Euston Road, London NW1 2BE, UK

**Dates:** Monday 21 & Tuesday 22, March, 2016

<b>Monday, 21 March 2016</b>	
9:00 AM - 9:30 AM	<b>Breakfast, Registration</b>
9:30 AM – 10:30 AM	<p><b>Welcome and Introductions:</b> Nicola Perrin, Wellcome Trust</p> <ul style="list-style-type: none"> <li>• <b>Overview of MRCT Center progress</b> in data sharing and rationale for current project</li> <li>• <b>Scope of the clinical trial data sharing program</b> – Vision and mission</li> <li>• <b>The Importance of Data Sharing and Transparency (EMA)</b></li> </ul> <p><b>Speakers:</b> Barbara Bierer, <i>MRCT Center</i> Fergus Sweeney, <i>European Medicines Agency</i></p>
10:30 AM - 11:10 AM	<p><b>Governance Workgroup</b> <i>The governance workgroup is tasked with developing the organizational structure and leadership for the new entity</i></p> <p>Key Workgroup Deliverables:</p> <ul style="list-style-type: none"> <li>○ Review Process</li> <li>○ Platform participating trials</li> <li>○ New Entity reveal</li> <li>○ Charter &amp; Governance structure</li> <li>○ Data Sharing Guidance and Resource Kit</li> </ul> <p><b>Presenter:</b> Rebecca Li, <i>MRCT Center</i></p> <p><b>Moderated Participant Q&amp;A</b> <b>Moderator:</b> Barbara Bierer, <i>MRCT Center</i></p>
11:10 AM - 11:25 AM	<b>Break</b>
11:25 AM - 12:15 PM	<p><b>Business Models Workgroup</b> <i>This workgroup's objectives are develop sustainable business models for the new entity</i></p> <p>Key Workgroup Deliverables</p> <ul style="list-style-type: none"> <li>○ Assumptions</li> <li>○ Case Studies</li> <li>○ Recommended funding and cost models</li> <li>○ Launch and long term sustainability needs</li> </ul> <p><b>Presenter:</b> Rohin Rajan, <i>Deloitte Consulting LLC</i></p> <p><b>Moderated Participant Q&amp;A</b> <b>Moderator:</b> Frank Rockhold, <i>Duke University</i></p>
12:15 PM - 1:00 PM	<b>Lunch</b>



1:00 PM – 1:30 PM	<b>EMA Policy 70 Implementation – Clinical Data Publication</b>  <i><b>Presenter:</b> Frances Nuttall, European Medicines Agency</i>
1:30 PM – 3:00 PM	<b>Data Sharing Platform Workgroup</b> <i>This workgroup's objectives are develop the IT blueprint including recommendations for the platform that would enable broader data sharing of clinical trials data</i> <ul style="list-style-type: none"><li>○ Data Sharing Platform – Overview</li><li>○ IT approach and summary of use cases</li><li>○ Key requirements for data packages</li></ul> <i><b>Presenter:</b> Ida Sim, University of California, San Francisco</i>  <b>Moderated Participant Q&amp;A</b> <i><b>Moderator:</b> Brian Bot, Sage Bionetworks</i>
3:00 PM - 4:30 PM	<b>Facilitated Discussion</b> <i>Facilitated discussion on vision, governance, sustainability, data sharing platform and clinical data publication (EMA). Invitation for collaboration, specific feedback, and constructive critique.</i>  <i>Break at 3 PM</i>
4:30 PM – 5:15 PM	<b>A Vision Comes Together</b> <i>Integrating the Governance, Business Models and Data Sharing Platform</i>  <i><b>Moderator:</b> Mark Barnes, MRCT Center</i>
5:15 PM – 5:30 PM	<b>Wrap Up Remarks: Day 1</b>  <i><b>Speaker:</b> Jeremy Farrar, Wellcome Trust</i>
6:00 PM	<b>Dinner at the Royal College of GPs</b> <i>30 Euston Square, London NW1 2FB, United Kingdom</i>

<b>Tuesday, 22 March 2016</b>	
8:00 AM - 8:30 AM	<b>Breakfast</b>
8:30 AM - 8:45 AM	<b>Day One Summary</b> <i>Speaker:</i> MRCT Center
8:45 AM - 10:00 AM	<b>Data Sharing Mandates</b>  <i>Speakers:</i> Jeffrey Drazen, <i>New England Journal of Medicine</i> Shasha Jumbe, <i>Bill and Melinda Gates Foundation</i> Joanne Waldstreicher, <i>Johnson &amp; Johnson</i> Bernard Lo, <i>The Greenwall Foundation</i>  <i>Moderator:</i> Barbara Bierer, <i>MRCT Center</i>
10:00 AM - 11:15 AM	<b>Moderated Panel Discussion</b> <i>Data Sharing Platform</i> <ul style="list-style-type: none"> <li>• Feedback on the proposed platform specifications</li> <li>• Challenges in implementation</li> <li>• Opportunity</li> </ul> <i>Panelists:</i> Adam Asare, <i>Immune Tolerance Network, Massachusetts General Hospital</i> Daniel Bergqvist <i>Google</i> Christoph Gerlinger, <i>Bayer Pharma Aktiengesellschaft</i> Vahan Simonyan, <i>US Food and Drug Administration</i> Kenji Takeda, <i>Microsoft Research</i>  <b>Moderated Participant Discussion</b> <i>Moderator:</i> Juergen Klenk, <i>Deloitte Consulting LLC</i>
11:15 AM - 12:15 PM	<b>Enabling, Harmonizing and Integrating Global Transparency Initiatives</b> Collaboration, Policy and Standards  <i>Panelists:</i> Robert Frost, <i>GlaxoSmithKline</i> Trish Groves, <i>BMJ</i> Rebecca Kush, <i>CDISC</i> Trudie Lang, <i>University of Oxford</i> Deborah Zarin, <i>National Institutes of Health (NIH)</i>  <b>Moderated Participant Discussion</b> <i>Moderator:</i> Jeffrey Drazen, <i>New England Journal of Medicine</i>
12:15 PM - 1:00 PM	<b>Lunch</b>



<p>1:00 PM - 1:45 PM</p>	<p><b>The Challenges of Data Privacy Laws Globally</b></p> <p><b>Speaker:</b> Nick Tyler, <i>Takeda Pharmaceuticals</i> Khaled El Emam, <i>Children's Hospital of East Ontario</i></p> <p><b>Moderator:</b> Beth Thompson, <i>Wellcome Trust</i></p>
<p>1:45 PM - 2:45 PM</p>	<p><b>One singular vision for the new entity - Uniting the platform, governance and business model</b></p> <ul style="list-style-type: none"> <li>• What are the challenges of this approach?</li> <li>• What are the benefits?</li> <li>• What assumptions must hold true for this approach to be successful?</li> </ul> <p><b>Next steps: Plan for next 18 months</b></p> <p><b>Moderated Participant Discussion</b></p> <p><b>Moderators:</b> Barbara Bierer, <i>MRCT Center</i> Mark Barnes, <i>MRCT Center</i></p>
<p>2:45 PM - 3:00 PM</p>	<p><b>Closing remarks</b></p> <p><b>Speaker:</b> Rebecca Li, <i>MRCT Center</i> Nicola Perrin, <i>Wellcome Trust</i></p>
<p>3:00 PM- 4:00 PM</p>	<p><i>Project leadership and Workgroup Members Debrief in Mendel 1</i></p>