AGENDA
FDA & MHRA Good Clinical Practice Workshop:
Data Integrity in Global Clinical Trials –
Are We There Yet?
Tuesday, October 23, 2018

8:00 AM  Registration Opens

8:50 - 9:00 AM  Administrative Announcements

9:00 - 9:10 AM  Welcome & Opening Remarks
David Burrow, Pharm.D., J.D., Director, Office of Scientific Investigations | CDER | FDA

9:10 - 9:25 AM  Key Note Speaker
Robert Temple, M.D., Deputy Director for Clinical Science | CDER | FDA

9:25 - 10:35 AM  Session 1 – Data Integrity from International Perspectives  (Moderator – Ni Khin)
Background and Purpose of Collaboration (15 min)
Ni Khin, M.D., Director, Division of Clinical Compliance Evaluation (DCCE), Office of Scientific Investigations (OSI), CDER, FDA
Gail Francis, Expert GCP Inspector, MHRA

Quality Management System/Quality by Design (QMS/QbD) (15 min)
Jean Mulinde, M.D., Senior Advisor, DCCE/OSI, CDER/FDA

Overview of Data Integrity (20 min)
Gail Francis, Expert GCP Inspector, MHRA

Good Clinical Practice Assessment of Data Reliability in Registration Trials (20 min)
Kassa Ayalew, M.D., M.P.H., Branch Chief, DCCE/OSI, CDER/FDA

10:35 - 10:50 AM  BREAK

10:50 - 12:05 PM  Session 2: Data Management  (Moderator – Kassa Ayalew)
Control and Quality of Clinical Data (55 min)
Andy Fisher, Lead Senior GCP Inspector, MHRA

The Data Management Plan – Pulling It All Together (20 min)
Cynthia Kleppinger, M.D., Senior Medical Officer, DCCE/OSI, CDER/FDA

12:05 - 12:30 PM  Q&A and Panel Discussion

12:30 - 1:30 PM  LUNCH  (Self-Pay)

1:30 - 2:45 PM  Session 3: Controlling Bias: The Study Blind  (Moderator – Cynthia Kleppinger)
Unblinding – Let Me Count the Ways (55 min)
Gail Francis, Expert GCP Inspector, MHRA
Jean Mulinde, M.D., Senior Advisor, DCCE/OSI, CDER/FDA

Blinding of Bioequivalence Trials (20 min)
Seongeun [Julia] Cho, Ph.D., Director, Division of Generic Drug Bioequivalence Evaluation, Office of Study Integrity and Surveillance (OSIS), CDER/FDA

2:45 - 3:00 PM  BREAK

3:00 - 4:00 PM  Session 4: Know Your Audit Trails  (Moderator - Jean Mulinde)
Design and Effective Use of Audit Trails (45 min)
Stephen Vinter, Operations Manager GLPMA & Laboratories Group, MHRA

A Case Example of the Review of Audit Trails in GCP Inspections (15 min)
Phillip Kronstein, M.D., Team Lead, DCCE/OSI, CDER/FDA

4:00 - 4:55 PM  Q&A and Panel Discussion

4:55 - 5:00 PM  Wrap-Up - Discuss Day 2 Case Study Expectations

5:00 - 6:30 PM  Networking Opportunity  •  TDCC Building 4 Lounge (Self-Pay)
# AGENDA
## Wednesday, October 24, 2018

**FDA & MHRA Good Clinical Practice Workshop:**

*Data Integrity in Global Clinical Trials – Are We There Yet?*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Moderator</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00 - 9:05 AM</td>
<td>Introductions - Case Studies</td>
<td></td>
</tr>
<tr>
<td>9:05 - 10:35 AM</td>
<td><strong>Session 1 - Case Studies on BE/GCP</strong> (Moderator - Cynthia Klempinger)</td>
<td></td>
</tr>
</tbody>
</table>
|             | **Vendor selection**                                                    | Sean Kassim, Ph.D., Director, Office of Study Integrity and Surveillance, CDER/FDA  
Stephen Vinter, Operations Manager GLPMA & Laboratories Group, MHRA |
|             | **Unblinding**                                                          | Charles Bonapace, Pharm.D., Director, Division of New Drug Bioequivalence Evaluation, OSIS, CDER/FDA  
Gail Francis, Expert GCP Inspector, MHRA  
Jean Mulinde, M.D., Senior Advisor, DCCE/OSI, CDER/FDA |
| 10:35-10:50 AM | **BREAK**                                                              |                            |
| 10:50 - 12:20 PM | **Session 2 - Case Studies on BE/GCP** (Moderator - Sean Kassim)       |                            |
|             | **Audit Trail**                                                         | Arindam Dasgupta, Ph.D., Deputy Director, DNDBE/OSIS, CDER/FDA  
Phillip Kronstein, M.D., Team Lead, DCCE/OSI, CDER/FDA  
Ruben Ayala, Pharm.D., Team Lead, DNDBE/OSIS, CDER/FDA |
|             | **Data Management**                                                    | Seongeun (Julia) Cho, Ph.D., Director, DGDBE/OSIS, CDER/FDA  
Andy Fisher, Lead Senior GCP Inspector, MHRA  
Cynthia Klempinger, M.D., Senior Medical Officer, DCCE/OSI, CDER/FDA |
| 12:20 - 12:50 PM | **Q & A Session**                                                       |                            |
| 12:50 - 1:00 PM | **Closing Remarks**                                                     |                            |

*Please keep up to date with future SBIA events by visiting:*

[SBIAevents.com](http://SBIAevents.com)