

# Clinical Trials Transformation Initiative (CTTI)

## ABDD Quality by Design Workshop

April 22 - 23, 2013

*Hyatt Regency Bethesda, Bethesda, MD*

### Attendee

| <b>Name</b>          | <b>Affiliation</b>                    | <b>Location</b>              |
|----------------------|---------------------------------------|------------------------------|
| Patrick Ajiboye      | Quintiles                             | Rockville, MD                |
| Patrick Archdeacon   | FDA                                   | Washington, DC               |
| Kassa Ayalew         | FDA                                   | Fort Belvoir, VA             |
| Mark Behm            | AstraZeneca                           | Wilmington, DE               |
| Helen Boucher        | Tufts Medical Center                  | Boston, MA                   |
| Robert Califf        | Duke Translational Medicine Institute | Durham, NC                   |
| Sabrina Comic-Savic  | The Medicines Company                 | Englewood Cliffs, NJ         |
| Edward Cox           | FDA                                   | Silver Spring, MD            |
| Aaron Dane           | AstraZeneca                           | Macclesfield, United Kingdom |
| Anita Das            | InClin                                | San Mateo, CA                |
| Helen Donnelly       | Northwestern University               | Downers Grove, IL            |
| Samantha Eells       | LA BioMed/Harbor-UCLA Medical Center  | Torrance, CA                 |
| Barry Eisenstein     | Cubist Pharmaceuticals                | Lexington, MA                |
| Vance Fowler         | Duke University                       | Durham, NC                   |
| David Friedland      | Cerexa, Inc.                          | Oakland, CA                  |
| Cami Gearhart        | Quorum Review IRB                     | Seattle, WA                  |
| Christine Ginocchio  | North Shore-LIJ Health System         | Brightwaters, NY             |
| Steven Gitterman     | FDA                                   | Silver Spring, MD            |
| Cheryl Grandinetti   | FDA                                   | Clarksburg, MD               |
| Sabine Haubenreisser | European Medicines Agency (EMA)       | Silver Spring, MD            |
| Dmitri Iarikov       | FDA                                   | Silver Spring, MD            |
| Brian Jamieson       | Cempra Pharmaceuticals                | Chapel Hill, NC              |
| Charles Knirsch      | Pfizer, Inc                           | Larchmont, NY                |
| Katherine Laessig    | FDA                                   | Silver Spring, MD            |
| Martin Landray       | University of Oxford                  | Oxford, United Kingdom       |
| Lisa LaVange         | FDA                                   | Silver Spring, MD            |
| Daphne Lin           | FDA                                   | Rockville, MD                |
| Debra Madden         | Patient Representative                | Newtown, CT                  |
| Ann Meeker-O'Connell | FDA                                   | Silver Spring, MD            |
| Steve Mikita         | Patient Representative                | Salt Lake City, UT           |
| Jean Mulinde         | FDA                                   | Owings Mills, MD             |

|                   |   |                   |
|-------------------|---|-------------------|
| Sumathi Nambiar   | FDA   | Silver Spring, MD |
| Gary Noel         | AstraZeneca   | Waltham, MA       |
| Janice Pohlman    | FDA   | Silver Spring, MD |
| David Rodin       | Pfizer, Inc.  | Morristown, NJ    |
| Daniel Rubin      | FDA   | Silver Spring, MD |
| Leonard Sacks     | FDA   | Silver Spring, MD |
| Jonas Santiago    | FDA   | Silver Spring, MD |
| Rachel Sherman    | FDA   | Silver Spring, MD |
| Kerry Snow        | FDA   | College Park, MD  |
| Brad Spellberg    | Harbor-UCLA Medical Center                          | Torrance, CA      |
| George Talbot     | Talbot Advisors LLC                                 | Anna Maria, FL    |
| Rose Tiernan      | FDA   | Silver Spring, MD |
| Joseph Toerner    | FDA   | Silver Spring, MD |
| John Tomayko      | GlaxoSmithKline                                     | Collegeville, PA  |
| Richard Wunderink | Northwestern University Feinberg School of Medicine | Chicago, IL       |
| Grace Yan         | FDA   | Silver Spring, MD |

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| <b>Name</b>     | <b>Affiliation</b>                        | <b>Location</b> |
|-----------------|---|-----------------|
| Noel Benedetti  | Clinical Trials Transformation Initiative | Austin, TX      |
| Cheri Janning   | Clinical Trials Transformation Initiative | Durham, NC      |
| Kunal Merchant  | Clinical Trials Transformation Initiative | Durham, NC      |
| Pamela Tenaerts | Clinical Trials Transformation Initiative | Durham, NC      |