The Future Unfolded: V1 of the TMF Standard Model

Gillian Gittens, Senior Director, TransPerfect Life Sciences

Lisa Mulcahy, Owner & Principal Consultant, Mulcahy Consulting, LLC

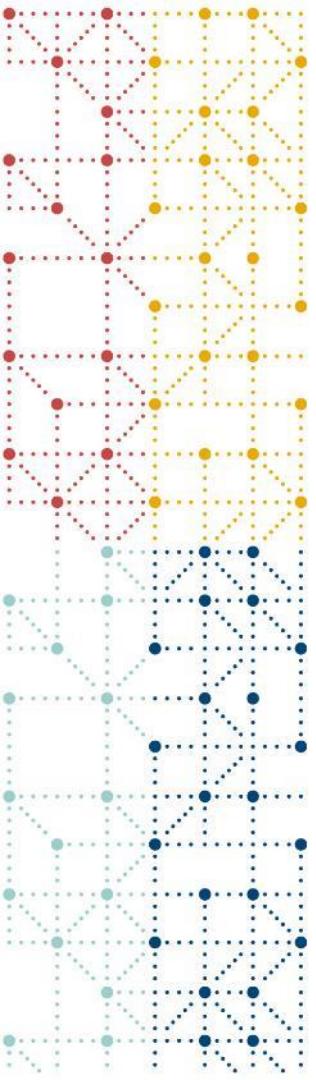**- Triage Committee Leads and Project Management Team Members**

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NASHVILLE

CONFERENCE & EXPO: 13-14 OCTOBER | TRAININGS: 15-17 OCTOBER

Meet the Moderators:

Gillian Gittens

Senior Director, Life Sciences
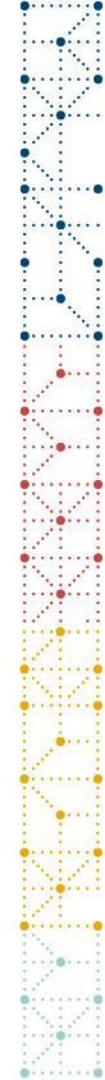TransPerfect

TMF RM V1 Association:

Co-lead of the TMF SM V1

Triage Committee
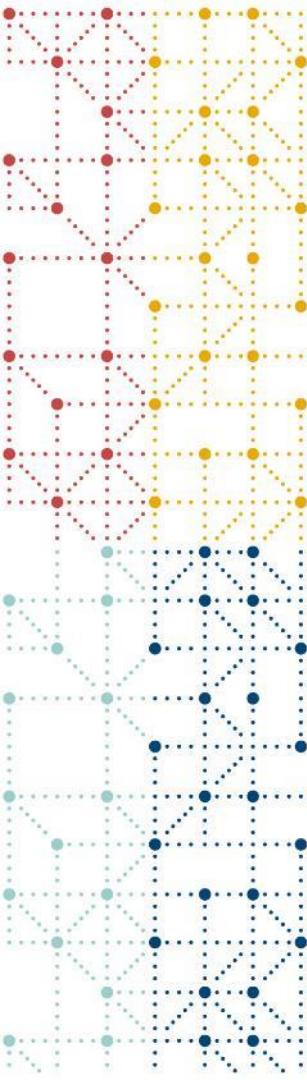
Lisa Dotterweich Mulcahy

Owner & Principal Consultant,
Mulcahy Consulting, LLC

TMF RM V1 Association:

Co-lead of the TMF SM V1

Triage Committee

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- *The views and opinions expressed in this presentation are those of the moderators and panelists and do not necessarily reflect the official policy or position of CDISC or any organization with which the presenters are employed or affiliated.*
- *The author(s) have no real or apparent conflicts of interest to report.*

Meet the Panelists

- **Paul Carter**

  Founder & CEO, Montrium

  TMF RM V1 Association:
  Chair of TMF RM Steering Committee
  V1 Management Committee Member

- **Donna Dorozinsky**

  Founder & CEO,
  Just in Time GCP

  TMF RM V1 Association:
  Lead for the V1 Project

- **Aaron Grant**

  Head of Innovation,
  Just in Time GCP

  TMF RM V1 Association:
  Workgroup Lead: Vendors and
  Metadata

- **Liz Farrell**

  Director, Compliance and TMF
  Oversight,
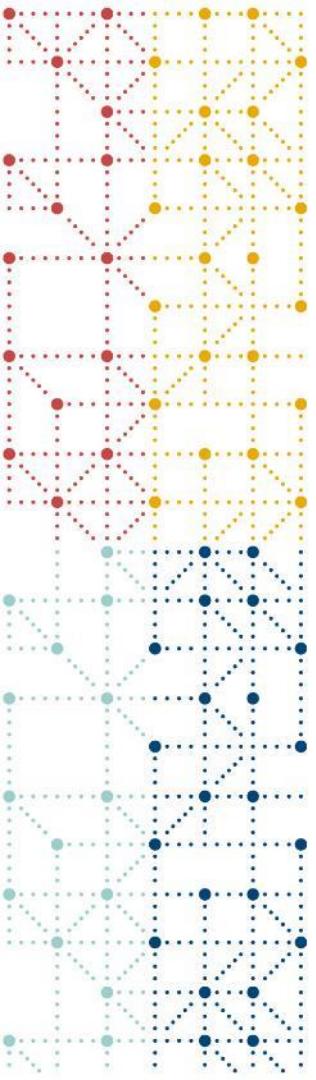 Agios Pharmaceuticals, Inc

  TMF RM V1 Association:
  Triage Committee Member

- **Jen Peacock**

  Associate Director, TMF Process &
  Systems,
  Biogen

  TMF RM V1 Association:
  Workgroup Lead: Computer System

Topics for Discussion:

1. Process and Timelines
2. Record Groups and Types and Change Management
3. Triage Committee and workgroup feedback review
4. TMF RM V1 as a Standard and RWE, Device, ISF
5. Vendors and Metadata workgroups
6. ICH GCP R3 workgroup
7. Computer System workgroup