



## CDISC USDM Governance Group (UGG) Volunteer Nomination Information Sheet

For members of the Digital Data Flow (DDF) Community



### Purpose of the UGG

The USDM Governance Group (UGG) provides oversight, guidance, and decision-making for the Unified Study Definition Model (USDM). Members ensure that changes to the standard are well-reasoned, stakeholder-aligned, and supportive of the broader Digital Data Flow vision.

Nominations are welcomed from the full spectrum of DDF stakeholders, including:

- Pharma and biotech digital protocol specialists
- Clinical operations and data standards professionals
- Technology and solution providers
- Vendors implementing USDM within their products and platforms

### Membership Tenure

- **1 year term**, with the option for an existing member to be nominated for **one additional year**.
- An **onboarding process** will ensure all new members are familiar with the governance workflow, decision-making expectations, and USDM processes.

### Baseline Competencies & Domain Knowledge

Nominees should bring a foundational understanding of the following areas to participate effectively in governance decisions:

#### Core Competencies

- Ability to evaluate technical proposals objectively and constructively
- Strong analytical and critical thinking skills
- Ability to synthesise stakeholder perspectives and identify impacts
- Clear communication skills for collaborative decision-making
- Comfort working in a consensus driven governance environment

#### USDM & DDF Domain Knowledge

- Understanding of the **Unified Study Definition Model (USDM)** concepts, structure, and purpose
- Familiarity with **Digital Data Flow (DDF)** principles and the end-to-end digital protocol lifecycle
- Awareness of how USDM is used by sponsors, vendors, and technology platforms
- Basic understanding of clinical study design and protocol elements
- Appreciation of interoperability standards (e.g., CDISC standards ecosystem, FHIR-based exchanges)

### Time Commitment

UGG members are expected to contribute consistently throughout the year:

#### Before new USDM development cycles

- Up to **4 one hour virtual meetings per month**
- Additional offline review time to evaluate governance requests

#### Outside development cycles

- **1-2 one hour virtual meetings per month**
- Ongoing offline review of proposals, clarifications, and change requests

#### Preferred Additional Participation

- Attendance at the **CDISC DDF SME bi-weekly meeting** is encouraged
- This group is consulted on governance items with broad stakeholder impact (e.g., major model extensions or structural changes)

### What UGG Members Contribute

- Informed, balanced governance decisions
- Representation of their stakeholder community
- Insight into practical implementation considerations
- Stewardship of the USDM as a shared, community driven standard

### Nomination Process

CDISC issues an annual call for nominations. Interested individuals may nominate themselves or be nominated by their organisation. All nominations are reviewed and approved by the **UGG Leadership Team (UGG-LT)** in consultation with the **UGG Team Leads**.