



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**.