CDISC Toolkit for Academic Professionals

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Meet the Speaker

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Yen is a science lecturer at Technological University Dublin and a founder of CodLad, a consulting firm dedicated to advancing data integrity and compliance through the implementation of CDISC standards in clinical trials. Her work bridges academia and industry, focusing on educating future data professionals and promoting regulatory readiness in academic research environments.

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Agenda

1. Project Background and Purpose
2. Toolkit Components
3. Evaluation Tools and Key Outcomes
4. Challenges and Lessons
5. Sustainability Strategy and Scalability Potential

Project Background and Purpose

Addressing the Academic Gap in CDISC Training

Background:

- CDISC standards are essential in clinical research but largely absent in academic programs.
- Graduates lack readiness to handle regulatory-compliant data upon entering the workforce.
- Industry spends time and resources training new hires on CDISC standards.

Implications:

- Slower onboarding into clinical trial operations.
- Reduced research efficiency and potential non-compliance with regulators.
- Limited participation in multi-center, data-standardized collaborations.

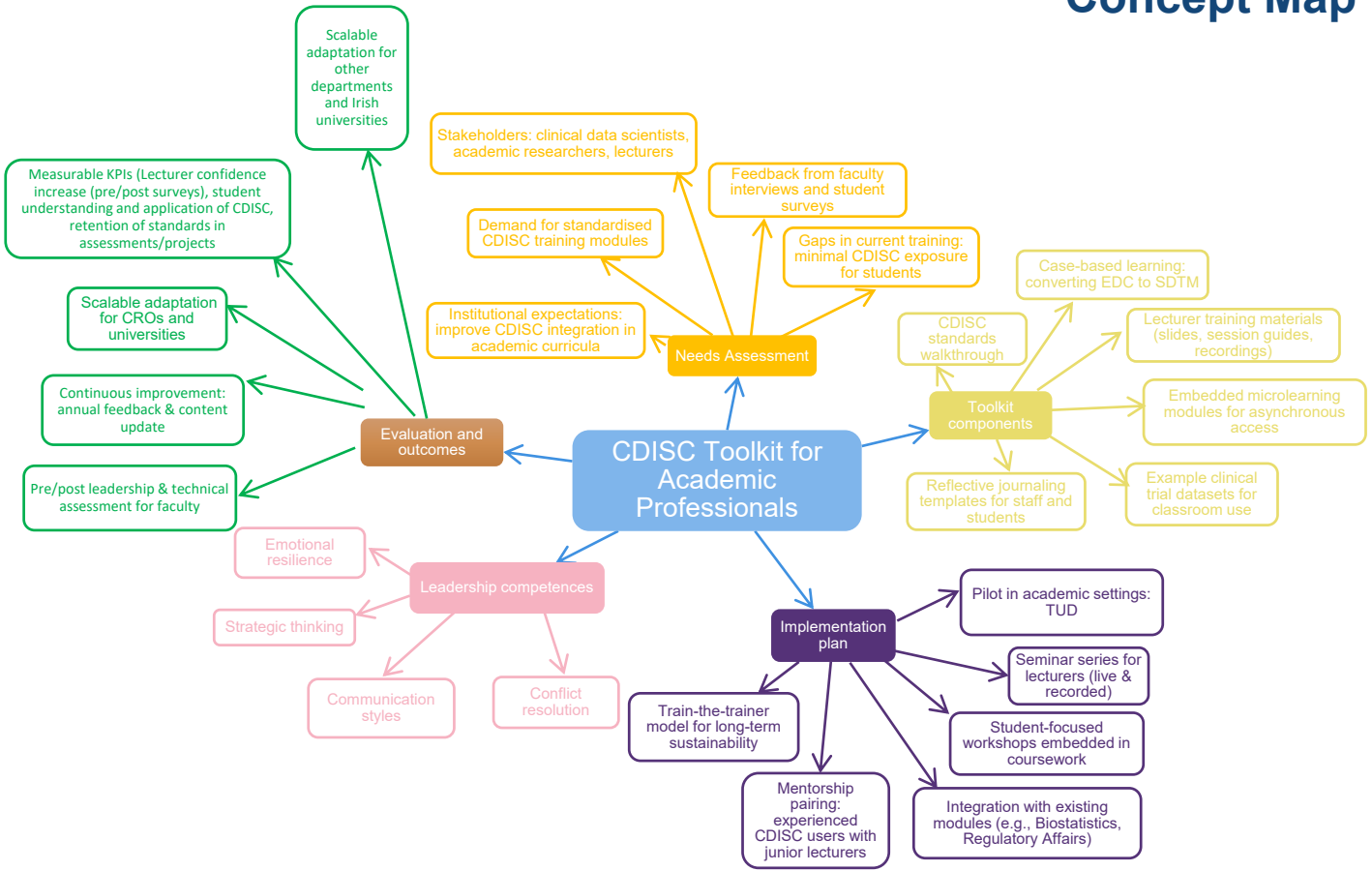
Project Purpose:

- Bridge the gap by developing a CDISC Toolkit for faculty training and curriculum integration.
- Pilot the toolkit at Technological University Dublin.
- Create scalable, evidence-based academic resources to embed CDISC standards into education.

Toolkit Components

Concept Maps, Logic Models, Modular Seminars and Practical Tools

Concept Map


CDISC Toolkit for Academic Professionals
Needs Assessment
Stakeholders: clinical data scientists, academic researchers, lecturers
Feedback from faculty interviews and student surveys
Gaps in current training: minimal CDISC exposure for students
Demand for standardised CDISC training modules
Institutional expectations: improve CDISC integration in academic curricula
Toolkit components
Case-based learning: converting EDC to SDTM
CDISC standards walkthrough
Lecturer training materials (slides, session guides, recordings)
Embedded microlearning modules for asynchronous access
Example clinical trial datasets for classroom use
Reflective journaling templates for staff and students
Evaluation and outcomes
Scalable adaptation for other departments and Irish universities
Measurable KPIs (Lecturer confidence increase (pre/post surveys), student understanding and application of CDISC, retention of standards in assessments/projects
Scalable adaptation for CROs and universities
Continuous improvement: annual feedback & content update
Pre/post leadership & technical assessment for faculty
Leadership competences
Emotional resilience
Strategic thinking
Communication styles
Conflict resolution
Implementation plan
Pilot in academic settings: TUD
Seminar series for lecturers (live & recorded)
Student-focused workshops embedded in coursework
Integration with existing modules (e.g., Biostatistics, Regulatory Affairs)
Mentorship pairing: experienced CDISC users with junior lecturers
Train-the-trainer model for long-term sustainability

Logic Model

Inputs
(Investment)

- Faculty time and expertise
- Access to CDISC documentation and tools
- Institutional support (TUD)
- Learning technology platforms (e.g., Moodle, Brightspace)

Outputs
(Activities)
(Participants)

- Develop lecturer training modules on CDISC (e.g., SDTM, ADaM, CDASH)
- Host seminars and train-the-trainer workshops
- Design microlearning modules and self-paced courses
- Implement reflective journaling practices for staff
- Number of workshops/seminars delivered
- Participants are lecturers

Outcomes- Impact

Short Term

- Increased faculty confidence teaching CDISC standards
- Positive feedback from workshop participants
- Initial integration of CDISC topics into existing modules

Medium Term

- Students apply CDISC principles in assessments/projects
- Standardization across academic clinical research output
- Increased inter-institutional collaboration on curriculum delivery
- More faculty become CDISC advocates or mentors

Long Term

- Graduates are better prepared for regulatory environments
- Sustained inclusion of CDISC in academic curricula
- Scalable toolkit adopted by other Irish universities
- Enhanced alignment between academic training and clinical trial industry demands

Assumptions

- Faculty are willing to adopt and integrate new material
- Institutional leadership supports standardization efforts
- CDISC standards will remain relevant and required by regulators

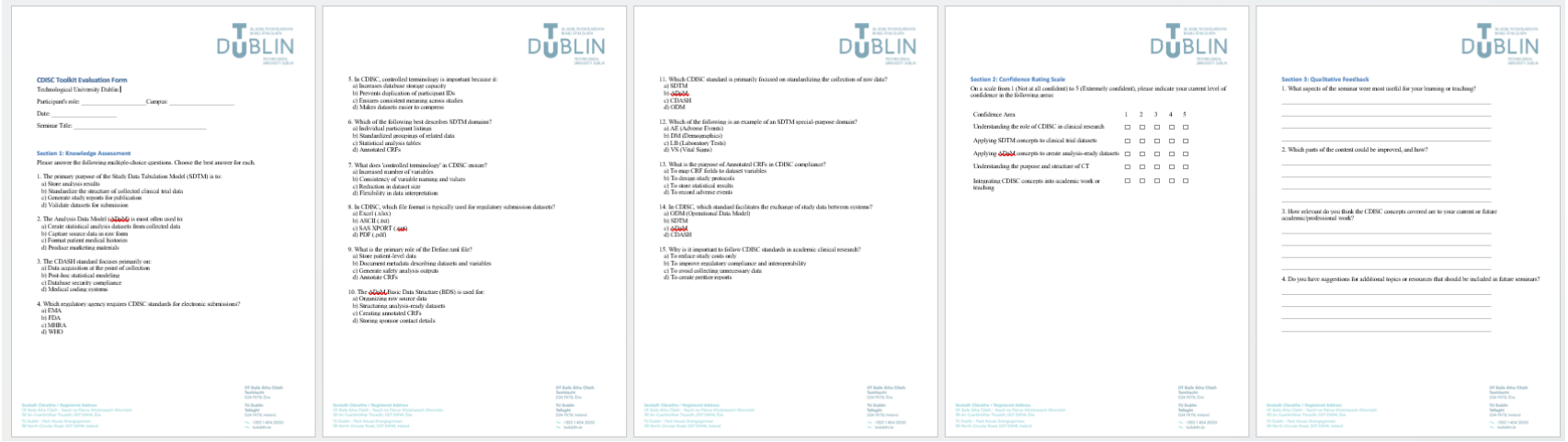
External Factors

- Changes in regulatory guidance (e.g., FDA, EMA)
- Technological updates in clinical data systems
- Variability in lecturer availability and student engagement

Evaluation Tools and Key Outcomes

Assessing Faculty Knowledge, Confidence, and Integration Readiness

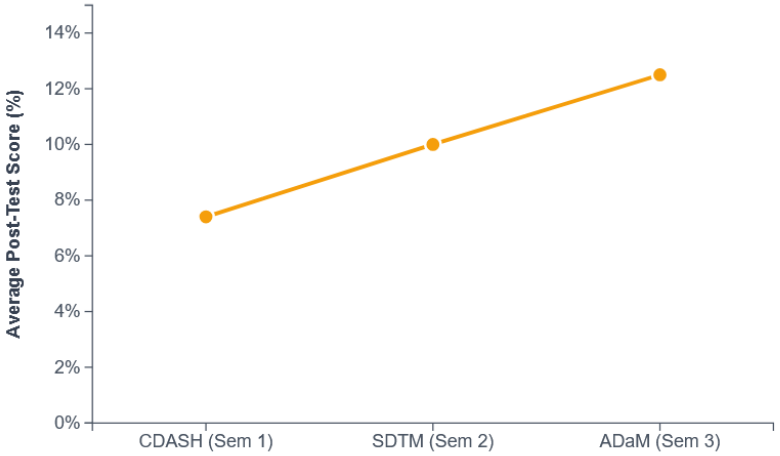
Evaluation Form

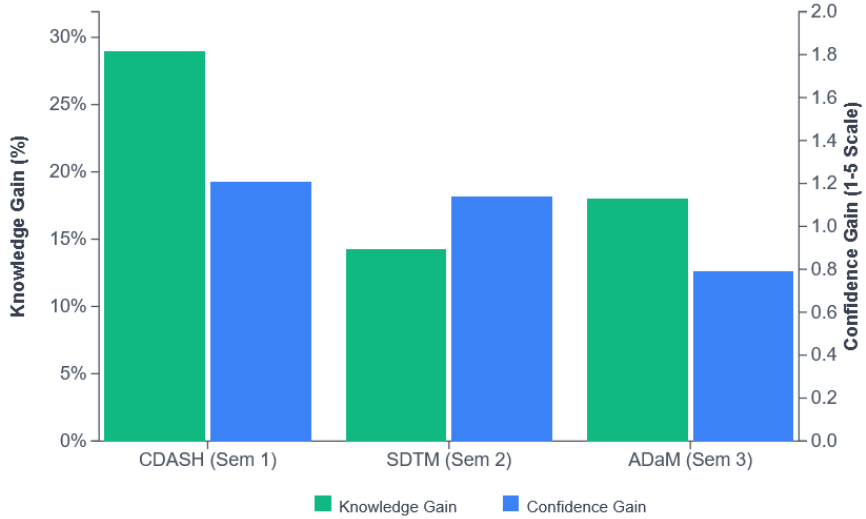


- Section 1: Knowledge Assessment
- Section 2: Confidence Rating Scale
- Section 3: Qualitative Feedback

Outcome

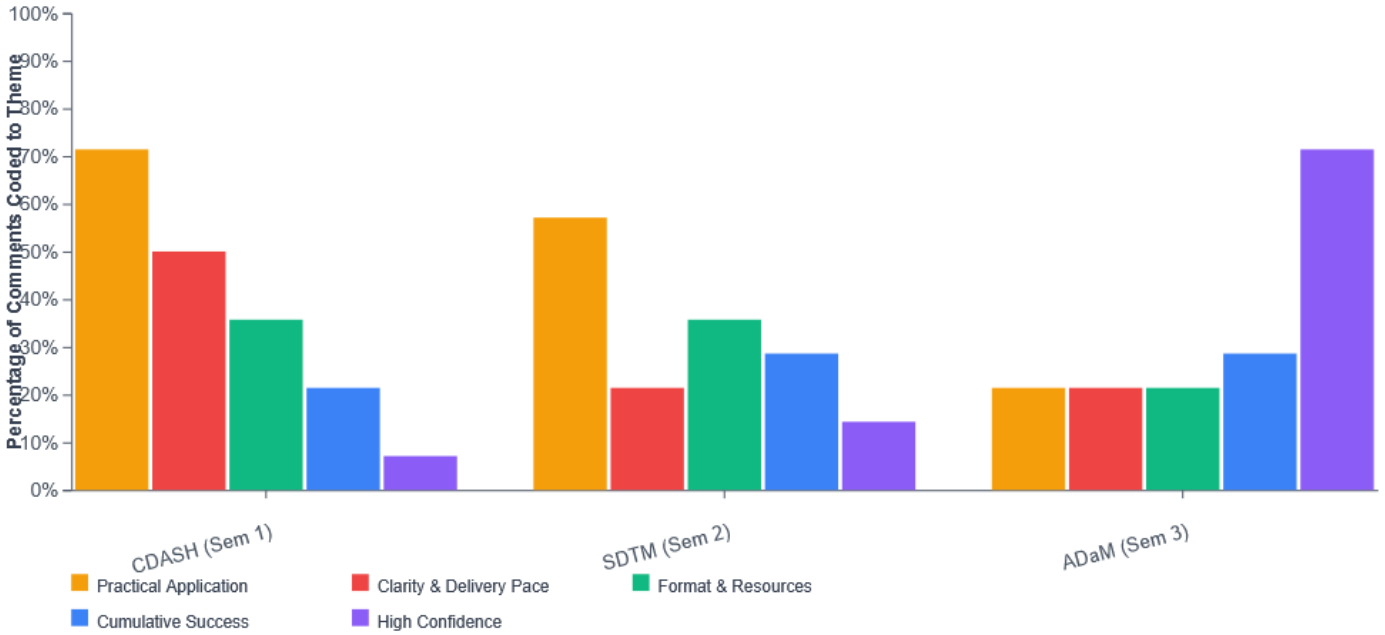
- Section 1: Knowledge Assessment & Section 2: Confidence Rating Scale





Outcome

- Section 3: Qualitative Feedback



Challenges and Lessons

Implementation Challenges:

- Some faculty members were unfamiliar with SAS export dataset formats.
- Not enough practices
- Overlaps occurred between seminar times and faculty teaching schedules.

Lessons Learned:

- Faculty expressed interest in additional hands-on sessions to reinforce CDISC application and retention.
- The planned 4th seminar faced low availability among participants due to time constraints.

Sustainability Strategy and Scalability Potential

Toward Institutional Adoption and Global Academic Impact

Institutional Sustainability:

- *Curriculum integration:* formalize the CDISC content by transitioning from optional seminars to mandatory course modules within BSc/MSc programs (e.g., Clinical Data Science, Biomedical Science).
- *Faculty training pipeline:* establish a **"CDISC Champion"** mentorship program using the successful pilot faculty to onboard new lecturers annually, ensuring knowledge retention.
- *Persistent resource platform:* digitize the toolkit into an evergreen, modular repository (e.g., institutional learning management system) to facilitate easy access, version control, and resource maintenance.

Scalability & Global Impact:

- *Formal train-the-trainer (TTT) model*: relaunch the 4th seminar as a Certified TTT Workshop focused on pedagogy and toolkit deployment, generating certified external faculty capable of replicating the training.
- *Modular toolkit architecture:* package CDASH, SDTM, and ADaM into self-contained, adaptable learning units that can be inserted into diverse academic curricula across different institutions.
- *Strategic academic partnerships:* leverage the pilot success to seed adoption across the Irish University Sector (IUS) and establish international partnerships with EU/US/Asia clinical research programs, supported by CDISC.
- *Measure institutional readiness:* develop a checklist for partner institutions to assess their capacity for CDISC integration, ensuring successful rollout.

Thank You!