

JAPAN ACADEMIC WORKSHOP

Friday, 17 November | 1:00pm - 5:15pm Japan Standard Time

Opening Remarks

Toshiki Saito J3C Vice Chair, NHO Nagoya Medical Center November 17th, 2023





Mission: さまざまなシステムや組織が連携でき、医学研究および医療の関連分野を改善する、プラットフォームに依存しないグローバルなデータ標準を開発およびサポートすること

- グローバルな非営利のSDO(Standards Development Organization:標準開発組織)
- 20年以上に渡り臨床データ標準の開発と実装
- 経験豊富なリーダーシップチームと40人以上の専門家を有する
- 1000人以上の業界の専門家によるボランティアネットワーク
- 500以上の組織が加盟
- 広く採用され、無料で利用できる臨床データ標準
- 成熟した標準ガバナンスプロセス
- 標準ライブラリとメタデータ管理のための革新的なオープンソーステクノロジー
- さまざまな新しい業界のイニシアチブとプロジェクトに関与
- パートナーシップによる協調的エコシステム
 - ・ メンバー、規制当局、患者団体、アカデミア、SDOおよび業界
- 健全な財務



Alliances and Collaborations

CFAST & Therapeutic Area Partnerships

CDISC collaborates with many organizations to develop Therapeutic Area (TA) standards for multiple disease areas through the Coalition for Accelerating Standards and Therapies (CFAST) initiative, as well as other partnerships.





Regulatory Collaborations

CDISC works closely with regulators around the world to ensure that CDISC standards will 1) streamline research from protocol/study design and trial registration through analysis and reporting; 2) facilitate the eSubmission review process; 3) ensure that clinical research is high quality; and 4) support the approvals of safe and efficacious medicines for patients.

Regulators also contribute to TA standards development



















Additional Collaborations

- Academic Institutions
- Accumulus Synergy
- BioPharmaceutical Statistics Leaders Consortium
- Clinical Data Privacy Consortium
- Learning Health Community
- Oxford University
- Phuse
- Pharmaceutical Data Standards Leaders
- Vivli









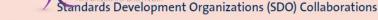
Organization for







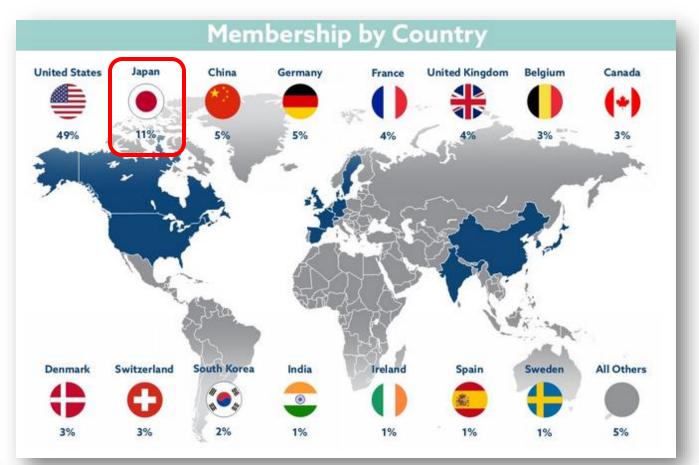




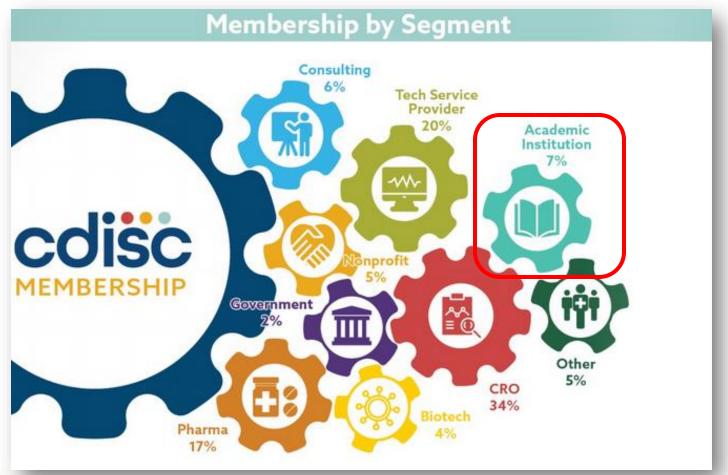
CDISC collaborates with other SDOs to develop standards that are synergistic to support a learning health system based upon high quality research.



CDISC and PhUSE partner to further the mission of each organization collectively, with CDISC focusing on the development of global, platformindependent data standards, and PhUSE focusing on the implementation and use of the CDISC standards. The two organizations work to combine efforts on key initiatives around end-to-end standards, TA standards, and semantics, strengthening an interdependent process.

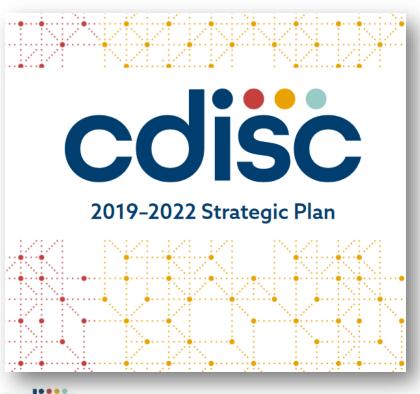








CDISC 2019-2022 Strategic Plan



- II.B. アカデミアをよりサポートするためのCDISC標準の拡張パイロット
- アカデミアユーザー向けの教育プログラムを拡張(II.B.1 Near-term:1.5 年以内)
- アカデミアのための戦略的ロードマップの確立(II.B.1 Medium-term:3年以内)
- アカデミアとのギャップを理解する。 アカデミアのニーズに対応するため のガイドラインを確立(II.B.2 Nearterm:1.5年以内)

https://www.cdisc.org/sites/default/files/resource/CDISC_2019_2022_Strategic_Plan.pdf



AcademiaにおけるCDISCの活用事例 Oxford大での事例

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

FEBRUARY 25, 2021

Dexamethasone in Hospitalized Patients with Covid-19

The RECOVERY Collaborative Group*

ABSTRACT

Coronavirus disease 2019 (Covid-19) is associated with diffuse lung damage. Gluco- The members of the writing corticoids may modulate inflammation-mediated lung injury and thereby reduce progression to respiratory failure and death.

In this controlled, open-label trial comparing a range of possible treatments F.Med.Sci., Andrew Ustianowski, Ph.D. in patients who were hospitalized with Covid-19, we randomly assigned patients to receive oral or intravenous dexamethasone (at a dose of 6 mg once daily) for up othy Felton, Ph.D., David Chadwick to 10 days or to receive usual care alone. The primary outcome was 28-day mortality. Ph.D., Kanchan Rege, F.R.C.Path., Chris Here, we report the final results of this assessment.

A total of 2104 patients were assigned to receive dexamethasone and 4321 to receive usual care. Overall, 482 patients (22.9%) in the dexamethasone group and M.D., Ph.D., Richard Haynes, D.M., and 1110 patients (25.7%) in the usual care group died within 28 days after randomization (age-adjusted rate ratio, 0.83; 95% confidence interval [CI], 0.75 to 0.93; integrity of this article. P<0.001). The proportional and absolute between-group differences in mortality The affiliations of the members of the varied considerably according to the level of respiratory support that the patients writing committee are listed in the Appenwere receiving at the time of randomization. In the dexamethasone group, the dix. Address reprint requests to Drs. Horby incidence of death was lower than that in the usual care group among patients and dinating Office, Richard Doll Bldg., Old receiving invasive mechanical ventilation (29.3% vs. 41.4%; rate ratio, 0.64; 95% Road Campus, Roosevelt Dr., Oxford OX3 CI, 0.51 to 0.81) and among those receiving oxygen without invasive mechanical 7LF, United Kingdom, or at recoverytrial@ ventilation (23.3% vs. 26.2%; rate ratio, 0.82; 95% CI, 0.72 to 0.94) but not among those who were receiving no respiratory support at randomization (17.8% vs. 14.0%; rate ratio, 1.19; 95% CI, 0.92 to 1.55).

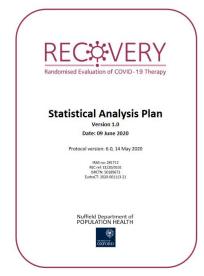
In patients hospitalized with Covid-19, the use of dexamethasone resulted in lower 28-day mortality among those who were receiving either invasive mechanical ventilation or oxygen alone at randomization but not among those receiving no respiratory support. (Funded by the Medical Research Council and National Institute for Health Research and others: RECOVERY ClinicalTrials.gov number. NCT04381936; ISRCTN number, 50189673.)

RECOVERY trial is provided in the Supplementary Appendix, available at NEJM.org

Drs. Horby, Lim, and Emberson and Drs Haynes and Landray contributed equally A preliminary version of this article was published on July 17, 2020, at NEJM.org.

N Fngl I Med 2021:384:693-704 DOI: 10.1056/NEJMoa2021436 Convirbt 40 2020 Manachusetts Medical Society 5.7 Data standards and coding terminology

> Datasets for analysis will be prepared using CDISC standards for SDTM and ADaM.





AcademiaにおけるCDISCの活用事例 Stanford大での事例

Article

CLINICAL TRIALS

Clinical trials in a COVID-19 pandemic: Shared infrastructure for continuous learning in a rapidly changing landscape 2021, Vol. 18(3) 324–334

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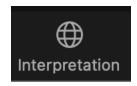
Haley Hedlin¹, Ariadna Garcia¹, Yingiie Weng¹, Ziyuan He², Vandana Sundaram¹, Bryan Bunning¹, Vidhya Balasubramanian¹, Kristen Cunanan¹, Kristopher Kapphahn¹, Santosh Gummidipundi¹, Natasha Purington¹, Mary Boulos¹ and Manisha Desai¹

- 共有インフラで少ないリソースでより堅牢な方法 で病気を評価する機会を 提供
- 時間とリソースの効率が 重要であるパンデミック時 には非常に価値がある
- 確立することは難しいかもしれないが、患者と研究者の両方に利益をもたらす

https://journals.sagepub.com/doi/pdf/10.1177/1740774520988298



Using Zoom's Interpretation Feature Zoom通訳機能の使い方



Simultaneous interpretation into Japanese will be available during the Englishlanguage presentations.

英語での発表時は日本語への同時通訳がつきます。

How to listen to Language Interpretation on Zoom:

- 1. Once you have logged into the Workshop, click the Interpretation button on your Zoom control bar.ワークショップにログインしたら、Zoom コントロール バーの [通訳] ボタンをクリックします。
- 2. Click on the language you would like to hear. 聞きたい言語をクリックしてください。
- 3. (Optional) If you prefer to only listen to the Japanese interpretation without the English speaker's voice in the background, you may select the **Mute Original Audio** option.英語話者の声をバックグラウンドにせずに日本語の通訳のみを聞きたい場合は、「オリジナルの音声をミュート」オプションを選択できます。



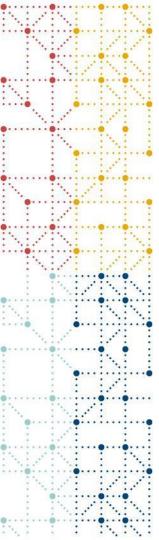
Additional Audience Questions



 Due to the limited time for each presentation, we may not be able to address your question during the Q&A. If you have a question we were unable to answer, we will collect those questions and share them with the presenters.

各プレゼンテーションには時間が限られているため、質疑応答ではご質問にお答えできない場合があります。お答えできなかったご質問につきましては、まとめて発表者と共有させていただきます。





Enjoy the Conference

