January 2013 eNewsletter

With the first Newsletter of the New Year, CDISC would like to wish you a happy, prosperous and healthy 2013! We are looking forward to a successful year through the significant participation of our working teams, members, and others who contribute to CDISC in many different ways. Your participation plays a major role toward achieving the CDISC mission and vision to inform patient care and safety through higher quality medical research!

The CDISC January Newsletter Presents the Following Topics:

- CDISC Asia-Pacific Interchange 2013
- CDISC Europe Interchange 2013
- CDISC Press Release-CDISC Announces New Additions to Board of Directors for 2013
- Study Design Standards
- Protocol Representation Toolkit - Beta Testing Period Comments Requested
- CDISC Technical News
- CDISC Office in Austin, TX
- Frequently Asked Questions
- CDISC Members Updates
- CDISC Coordinating Committees Updates
- CDISC User Networks
- Opportunity to Donate to CDISC
- CDISC Volunteer Opportunity
- Job Opportunities Available
- Global Events and Education Opportunities
- CDISC Official Primer for a Lower Price
- CDISC Social Media

Announcing the Inaugural CDISC Asia-Pacific Interchange: “Streamlining Global Research through Standards”

Don’t forget to register for the upcoming CDISC Asia-Pacific Interchange, to be held 18-22 February in Singapore! We have an ‘all-star’ line-up of speakers for this event. This conference offers attendees the rare opportunity to collaborate and gain information about best practices in clinical data standards implementation and streamlining clinical research from global leaders, all practically from their doorstep!

Date:
18-22 February 2013
CDISC Authorized Education Courses on 18-19 & 22 February
Main Conference 20-21 February

Location:
2 Stamford Road
178882 SINGAPORE

Program Available HERE

Example of Conference Speakers:

- Dr. Greg Koski (ACRES)
- Dr. Yasuo Ohashi (University of Tokyo)
Conference Topics:

- Introduction to CDISC
- Case Studies with CDISC Standards
- Status of Clinical Research around the Globe
- Clinical Research and EHRs
- CDISC in the Asia-Pacific Region
- Global Standards Harmonization
- Therapeutic Area Specific Standards

Special Discount to the Conference:

Individuals who attend any 2 training courses are eligible to receive a special discount on their attendance during the conference days! Details below:

- **CDISC Members:** In addition to the original CDISC Member Discount (40% off for Platinum members; 20% off for Gold members), those that attend any 2 training courses will be eligible for an additional 10% discount off the conference price! Fill out the **Offline Registration Form** to ensure that your invoice will reflect this discount!

- **Non-Members:** Individuals from non-member companies will get a 20% discount off of the original price. Fill out the **Offline Registration Form** to ensure that your invoice will reflect this discount!

**Act quickly! Special Pricing Discounts will end on 8 February!**

- **Register Offline HERE!**
- **Register Online HERE!**

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**For more information, visit us at the CDISC Website.**

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**Pharmaceutical Users Software Exchange (PhUSE) Inaugural Single Day Event in Hyderabad, India**

Planning to attend the upcoming CDISC Asia-Pacific Interchange in Singapore? If you are free the day after the conference ends, you should also consider heading over to Hyderabad, India for our partner organization, PhUSE’s, inaugural Hyderabad Single Day Event, to be held 23 February 2013. Details can be found on the PhUSE website HERE. **Follow the link for more details.**

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**CDISC Europe Interchange 2013**

**The CDISC Europe Interchange 2013** [1] will be held on 22-26 April 2013 in Frankfurt, Germany. Don’t miss out! Hear from industry leaders and FDA and IMI representatives, and play an essential role in supporting the CDISC vision: to Inform Patient Care & Safety Through Higher Quality Medical Research. Dr. Michel Goldman, head of the Innovative Medicines Initiative (IMI) will be our keynote speaker. The latest achievements and recent regulations in research will be presented at the conference allowing our audience to share experiences and ask related questions.

Registration for the conference and authorized CDISC educational courses is available through this link. [1]

Submission of Abstracts for the CDISC European Interchange is extended till Tuesday, 22 January 2013. Time is limited! Submit your abstracts through this link. [1]
Join us at our EU Interchange Evening Networking Event

CDISC Interchanges bring joy to our loyal members and audiences. At this EU Interchange, you will be treated to a live music show featuring Elvis Presley music (in honor of the Interchange location at the site where Elvis spent two years of his life). This Networking Event will take place on the evening of the first conference day; the live music show will be followed by dinner on stage with background live music indulging our attendees with a nice atmosphere of networking and chatting.

Mark your calendars! The CDISC International Interchange will take place in Bethesda, MD on 4-8 November 2013.

Sponsorship Opportunity at Our Interchanges.

Bring greater awareness of your organization’s mission and involvement in the global healthcare community. Expand the visibility of your organization to all our international members and non-members through sponsoring and/or exhibiting at our events. Benefits of sponsorship are significantly revealed through displaying your logo on our press releases, programs and website, as well as on our Interchange signage and through the screens at the conference venue. Further details on sponsorship can be found here.

Furthermore, exhibiting at our event will provide your company the opportunity of interacting with key international organizations and global regulatory entities who will be attending the CDISC Interchange.

- Follow the link if you are interested in exhibiting at the CDISC Europe Interchange 2013.
- And view the following link for exhibiting opportunities at the Asia-Pacific Interchange 2013.

CDISC Press Release-CDISC Announces New Additions to Board of
CDISC is pleased to announce that five highly qualified individuals will add invaluable expertise to the CDISC Board of Directors (BoD) for a three-year term beginning this month (2013—2016). Dr. Carolyn Compton, Michael Glickman, Dr. Douglas Peddicord, Stephen Pyke, and John Speakman each contribute unique skillsets to the BoD that will greatly assist CDISC as it moves forward with its Strategic Goals in 2013. Sincere appreciation goes to Dr. Steven Hirschfeld and Robert Goodwin, who completed their CDISC Board service in December 2012 and to Wayne Kubick who has become the Chief Technology Officer for CDISC. Follow the link for information about each of these new Directors.

CDISC Success Story

In an attempt to increase value for its stakeholders, CDISC has initiated the feature of Success Stories in 2012. These stories reflect experiences with the CDISC standards and how they continue to bring success and add efficiency to the work environment. If you would like to present your success story with CDISC in a future Newsletter, please contact Diana Harakeh. This month, our topics discuss the Study Design Standards and the Protocol Representation Toolkit.

Study Design Standards

Study Design Standards: An Overview

Study Design is a critical activity in the lifecycle of a clinical research study. It is the foundational blueprint for the execution of the study, forming the basis for the study protocol.

Because of its importance in a study, the research protocol information is not only used throughout the study, but is also requested by regulatory authorities such as the US FDA and study registries worldwide such as WHO, the European Medicines Agency and US clinicaltrials.gov.

Even for protocols with complex study designs, each research study has common information that has been standardized to enable data sharing and aggregation. This common information includes eligibility criteria, the schedule of planned assessments and interventions, and the experimental design (including arms, epochs, randomization points and more).

Several standards currently exist to address protocol representation. The CDISC Protocol Representation Model (PRM) addresses all of the aforementioned common information: eligibility criteria, study design, and study registration. This article focuses on the standards that relate directly to the study design part of PRM.

BRIDG: The Standard for Study Design Semantics

The Biomedical Research Integrated Domain Group (BRIDG) Model was started by CDISC in 2003 to support the harmonization of all CDISC standards as well as to support the research link with healthcare. Since then, BRIDG has become a collaborative effort engaging stakeholders from CDISC, the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM) Work Group, the US National Cancer Institute (NCI), and the US Food and Drug Administration (FDA). The goal of the BRIDG Model is to produce a shared view of the information used in protocol-driven research and its associated regulatory artifacts so that information can be reliably exchanged and aggregated.

Click here to view more about the CDISC Protocol Representation Model (PRM), CDISC SDTM Trial Design Model (SDTM TDM), CDISC Study Design Model - XML, HL7 Clinical Trial Registration and Results and HL7 Study Design Structured Document (HL7 SD SD).

Protocol Representation Toolkit – Beta Testing Period Comments Requested

The leader of the CDISC Protocol Representation Group (PRG) presented via an online webinar on 18 December 2012 where more than 200 attendees joined the webcast from various regions of the world. The PRG has worked for the past decade under an overall charter and a primary objective for standardizing and structuring the content of the Research Protocol document. The Protocol Representation Model (PRM) v1.0 was published in 2010. A more recent objective of this CDISC team is to facilitate the use of this standard by creating tools around using these standardized concepts. Furthermore, the relationship between the PRM and SDTM is extremely important to the PRG. The tool and this relationship were the primary topic for this webinar.

The PRG has ensured alignment of the PRM with the CDISC BRIDG model while releasing the initial tool, which is based around Study Online Concepts (including standards concepts and standard document layout). In addition, the Protocol team continues work to create the standard list of concepts for the entire Protocol; this comprehensive set of concepts is an activity for this team in 2013.

The Study Outline Web-Wizard Tool: This tool is an online web-based accessible tool available on the CDISC website for all CDISC members. Click here for further information on the CDISC PRM Toolset Version 1.0.

We have the benefit of the standardization, but we need to know how to apply these standards in the business process (for
CDISC Technical News

CDISC is continuously working on many projects to develop or enhance standards to support our mission and vision. Visit our website for frequent updates on CDISC standards currently posted for public review and comment or available for use.

Last month saw the provisional release of the SDTM Implementation Guide for Medical Devices and new therapeutic area user guides for Virology and Parkinson's Disease. A collection of 7 new domains as part of SDTMIG v3.1.4 batch 2 was also released and is still open for comment. In the coming weeks, CDISC expects to post the provisional user guide for Polycystic Kidney Disease, and final version of Define-xml v2.0. Among documents slated to be released soon for public comment are:

1. A new draft user guide describing how to organize and submit cardiovascular data using standard SDTMIG domains.
2. A new CDASH supplement for collecting Serious Adverse Event data to support expedited reporting consistent with ICH E2B.

We are also planning to expand availability of a new web-based Study Outline Web Wizard tool for use with the CDISC Protocol Representation Model. Later in Q1 we expect to release the 2013 technical plan, which will list other major projects and deliverables targeted for this year.

Follow the link for Standards open for review and comment as well as new standards available for use. Stay tuned to our homepage for details on Standards and Technical updates as well as current CDISC information.

CDISC, together with the Analgesic Clinical Trial Translations Innovations, Opportunities, and Networks (ACTTION) (http://www.acttion.org) group, is releasing v1.0 of the Pain Therapeutic Area Supplement to the Study Data Tabulation Model User Guide.

Follow the link for an interesting article on "A standard database format for clinical trials of pain treatments: An ACTTION-CDISC initiative".

Join us for the CDISC Standards Webinar on Thursday, 31 January 2013 at 11:00 AM U.S.A Eastern Time.

Please follow the link to attend.

CDISC Registered Solution Provider:
CDISC will be enhancing the Register Solution Provider (RSP) Program in the near future - Watch the CDISC website for the announcement soon!

Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials. Please see the latest on "Conducting Clinical Research in the Informational Age".

CDISC Office in Austin, TX!
The CDISC Office, which is located in the Texas Medical Association building in the heart of Austin, TX, right next to the Texas State Capitol and in the middle of the commercial region of the city, has become the official headquarters of the CDISC organization.

If you happen to be in the area, please let us know so that we can organize a time for you to come visit us. Our new address is: 401 West 15th Street, Suite 975, Austin, TX 78701. We now have the opportunity to host local meetings and conferences. The first public event, a free educational event “A Global Approach to Accelerating Medical Research”, occurred on 13 December 2012 at the Auditorium of the TMA building. The Learning Health System Summit will follow on 5 February 2013 at the most amazing TMA conference room, The May Owen Board Room.

CDISC vital participation in the global healthcare community will continue to be pursued through our international members and teams working together towards accelerating medical research for our patients' safety and wellbeing.

**Frequently Asked Questions**

We are constantly updating the Frequently Asked Questions area of the CDISC website to make it easier for our readers and CDISC followers to find their answers. This month we would like to draw your attention to the following areas:

- Who owns CDISC Standards?
- How does CDISC offer its standards openly and freely?
- What CDISC standards are ready to implement?
- Why use the CDISC standards? What are the values of the CDISC standards?
- What is the CDISC Technical Roadmap?
- What is the Protocol Representation Model (PRM) Toolkit?
- Can the Protocol Representation Model Be Used without the Toolkit?
- Why is the New PRM Toolkit Only Available in the Members Only Area?
- Where does CDISC get its funding?
- Are EHRs ready to support regulated clinical research studies?
- Will CDISC SDTM be mandated by the US Food and Drug Administration (FDA)?
- What should I do if I want to make a regulatory submission to FDA using CDISC standards?
- What is the CDISC IP Policy? Why does CDISC have such a policy?
- What other policies does CDISC have?

Follow this link for answers.

**CDISC Members Updates**

**New Gold Members in December:**
- Exelixis, Inc.
- MacroGenics, Ltd.

**New Platinum Member in December:**
- Fujitsu Limited

Thank you and a warm welcome to our new members in December. The CDISC community continues to grow and we encourage you to reach out and connect with fellow members and CDISC staff via the various forums provided by CDISC.
Communications.

**Star Members in December:**
- Baxter Healthcare Corporation
- Instem LSS
- Velos, Inc.

**CDISC ST★R MEMBERS**

We want to take this opportunity to recognize and thank all our Star Members for your continuing support of our mission and goals and look forward to many more years of great collaboration between your organizations and CDISC.

We could not have done it without you...

Rebecca Kush  President & CEO  Velos, Inc.
Shelia Leaman  Global Solutions Manager  Instem LSS

Click here to see our ST★R MEMBERS.

Non-Members can enjoy all our benefits and more by joining CDISC! Please contact membership@cdisc.org for further details.

**CDISC Global Coordinating Committees (3Cs) Latest Updates**

To express our deep appreciation to our global CDISC coordinating committees (3Cs), we have launched a special section on our website to display the CDISC Coordinating Committees latest achievements and accomplishments in relation to CDISC clinical research standards and global healthcare. Click here to view the 3Cs page.

**The European CDISC Coordinating Committee (E3C) Latest Updates**

The E3C has completed its election process in November 2012, during which they elected the following exceptional members to support the CDISC mission and vision by being 3C members in Europe:

- Carine Javierre of Sanofi
- Nathalie Sabine of Clinical Data
- Mark Lambrecht of SAS
- Andrea Rauch of Boehringer-Ingelheim
- Stephen Pyke of GSK (and a new CDISC Board Member)

The E3C is organizing the CDISC European Interchange this year; it is scheduled for 22-26 April 2013 in Bad Nauheim/Frankfurt, Germany. In addition, the E3C will hold a face-to-face meeting 23-24 January 2013 to review / discuss the EU Interchange abstracts and go over preparations and agenda for 2013 in relation to their continuous support to the CDISC organization in Europe.

**The Japanese CDISC Coordinating Committee (J3C) Call for Nominations and Latest Updates**

The J3C has announced a Call for Nominations for J3C members

The main responsibilities of the J3C include:

1. Develop an action plan each year, in collaboration with CDISC Executive Operations, that is aligned with the CDISC
Strategic Goals and the CDISC Operational Goals for that year.

2. Organize and promote CDISC Interchanges in Japan with prior approval of dates, contracts and other related obligations from CDISC Executive Operations.

3. Provide assistance regarding the scheduling and content of authorized training and other educational seminars in Japan, working with the CDISC lead for Education.

4. Liaise with Japanese regulatory authorities, other appropriate institutions and standards developing organizations in close collaboration with CDISC Executive Operations.

5. Form value-added collaborations with organizations in Japan that can further the CDISC vision and mission communicating interactions to CDISC Executive Operations.

6. Assist in the creation and coordination of User Networks/User Groups in Japan, as appropriate, and ensure that the feedback from the User Networks / User Groups is consolidated and communicated back into the CDISC through the CDISC Executive Operation liaison to the 3C and CDISC Communications representative.

7. Place documentation for the J3C in the CDISC Portal and communicate activities through CDISC website and eNewsletters.

Applicants from IT vendors, Academia/Hospital and SDOs should represent CDISC member organizations and must support the CDISC mission and understand the value of the CDISC Data Standards. They agree to actively support the development, adoption and implementation of the CDISC Data Standards. They must also have the capacity to make their time available for their J3C duties. These include attending 3 face-to-face meetings a year, attending monthly teleconference calls and undertaking individual tasks. In addition, applicants should be Japanese.

Candidates can nominate oneself or others for a J3C position. Candidates must provide a resume and a motivation letter expressing their interest to be on the J3C. If you feel the J3C is an organization you would like to be a part of, please provide your CV and a motivation letter to Diana El-Harakeh by Friday, 15 February 2013.

J3C and CDISC Japan User Group (CJUG) Latest Meetings and Activities

CJUG recently hosted a CDISC SDTM Team meeting on Friday, 14 December 2012 at TIS Inc. in Japan with 28 people attending. Their second SDTM Team meeting was scheduled on Friday, 11 January 2012 at Astellas Pharma Inc., and 26 people attended this meeting. Attendees discussed a number of topics including: (1) participation in the Protocol team (PRG); (2) SDTM Data Implementation; (3) member affiliation; and (4) possibly establishing CRF, Trial Design Model and EDC groups in the future. Finally the day closed with a presentation entitled ‘Overseas Trend Use Document Management System in Clinical Trials’.

The next SDTM Team meeting will be held on 8 February 2013 at Chuo-Ku Nanakuminkan (Kyobashikuminkaikan) in Tokyo. The meeting is scheduled from 13:00 to 17:00, and the following topics will be discussed:

- Presentation on “You want to use CDISC Submission Values for Analysis Results?” By LiGaS which is an SDTM Sub-Team.
- SDTM Data implementation activity sub group meeting will be held during the second session to discuss the following:
  1. Create CRF group
  2. Create Trial Design Model group
  3. EDC Builder group
  4. Protocol group

The day will be concluded with a presentation from Mr. Takekuma of Medical Information System Development Center (MEDIS-DC), who will present on ‘About Standards Code’. MEDIS-DC is an agency with an established disease code (For EHR/ICD10) and LAB code (JLAC10/Like LOINC code) in Japan.

In addition, the upcoming CJUG Workshop will be held on Tuesday, 12 March 2013 from 10:00 to 17:00 at CAC EXICARE in Japan.

The Chinese CDISC Coordinating Committee (C3C) Call for Nominations and Latest Updates
The Chinese CDISC Coordinating Committee (C3C) is an organization founded to support global CDISC initiatives in China and to provide regional feedback to the central CDISC organization. The C3C recently held a face-to-face meeting to discuss the recruitment of additional members to support CDISC activities in 2013. According to the new CDISC Coordinating Committees (3C) charter, each committee should consist 12 members maximum. Currently, the C3C consists of 10 members with two new positions open to candidates.

The C3C would also like to nominate another vice-chair, in addition to Victor Wu, who is the current vice-chair of the committee.

The primary responsibilities of the C3C include:

1. Organization of annual CDISC Interchanges in China with prior approval of dates, contracts and other obligations from CDISC Executive Operations.
2. Assistance in scheduling and coordinating authorized CDISC training and other educational seminars in China, liaising with the CDISC Executive lead for Education.
3. Liaison with regulatory authorities in China, other appropriate health institutions and standards developing organizations, working in close collaboration with CDISC Executive Operations.
4. Establish value-added collaborations with organizations in China that can further the CDISC vision and mission, communicating interactions to CDISC Executive Operations.
5. Overseeing the creation and coordination of any User Networks/User Groups in the region as deemed appropriate, ensuring feedback from the User Networks / User Groups is consolidated and communicated back into the CDISC organization.

Membership in the C3C will provide a unique opportunity to give support and feedback to the CDISC organization. C3C members represent CDISC in China!

Applicants must support the CDISC mission and understand the value of the CDISC Data Standards. They agree to actively support the development, adoption and implementation of the CDISC Data Standards. They must also have the capacity to make their time available for their C3C duties. These include attending face-to-face meetings, attending monthly teleconferences and undertaking individual tasks. In addition, applicants must reside in China.

Candidates can nominate oneself or others for a C3C position. Candidates must provide a resume and a motivation letter expressing their interest to be on the C3C.

If you feel the C3C is an organization you would like to be a part of, please provide your CV and a motivation letter to Sheila Leaman.

Note that the 3C Charters have now been updated and combined into a common CDISC Operating Procedure (COP). The penultimate version has been approved by the C3C, J3C and E3C and will be posted within the next two weeks on the CDISC website under ‘About CDISC’. The User Network COP is already posted in this location.

CDISC User Networks

CDISC User Networks have been formed all around the globe in Africa, Asia, Europe and the United States of America. User Networks enable face-to-face interactions to encourage the adoption of CDISC standards by sharing implementation experiences in various global communities and regional areas. They play an essential role in expanding the CDISC international presence.

The CDISC Boston Area User Network (BACUN) held a meeting on 11 January 2013 at Shire Pharmaceuticals in Lexington, MA. Current status and highlights from CDISC teams (SDTM 3.1.4, Oncology, Questionnaires, Devices, SHARE, FDA public meeting and more) were presented. Governance for CDISC Standards was also presented through a panel discussion with the audience and finally the meeting was concluded with a steering committee lunch to help plan and organize for future BACUN meetings.

To join a CDISC User Network, feel free to contact Diana Harakeh. The User Network portal area is open to anyone and provides information on specific User Networks, including announcements of their next meetings.

Follow the link to know more about the purpose and benefits of the CDISC User Networks.

Donate to CDISC
The U.S. Internal Revenue Service (IRS) approved CDISC as a 501(c)(3) organization in December 2011, recognizing it as a charitable organization retroactive to May 2011.

With our current ability to receive tax-deductible contributions from individual and corporate donors, we will promote CDISC’s message to a broader audience, enhancing CDISC’s capacity to locate funds through diverse means. Your contribution will help us accelerate the availability of new medical therapies to patients in need. Follow the link to know more about how to make your valuable donation.

**CDISC Depends on Volunteers to Develop and Maintain Our Open Standards**

Engage yourself with the CDISC mission and vision to inform patient care and safety through higher quality medical research and join our working teams by volunteering to any of the following areas:

- XML Afficionados
- Technical Writers
- Protocol Representation
- Device Terminology Specialist

Follow the link to know more about how to volunteer! Further questions, please email us here.

**Job Opportunities Available**

- **Job Position Available at CDISC: IT Applications Support Specialist**
- **Job Position Available at CDISC: Project Manager - Standards Development**
- Medical Science & Computing, Inc. (MSC) is searching for a Biomedical/Clinical Research Information Specialist to support the NIH.

**CDISC Global Events and Education Opportunities**

**CDISC Interchanges:**

- **CDISC Asia Interchange in Singapore, 18 - 22 February 2013.** Offline and Online Registration are Available.
- **CDISC Europe Interchange in Germany, 22 - 26 April 2013.** Offline and Online Registration are Available.
- **CDISC International Interchange in North Bethesda, MD, 4 - 8 November 2013.** Registration and details will be available soon.

Join us for the **CDISC Standards Webinar** on Thursday, 31 January 2013 at 11:00 AM U.S. Eastern Time. Please follow the link to attend.

CDISC Webinars for 2013 will be posted through this link. Stay tuned for more information!

**Authorized Courses:**

Did you know that CDISC Education provides the only authorized courses on CDISC standards? Find out more here.

**Private Courses:**

We can provide in-house courses to any organization, in most places in the world. To find out how you can bring CDISC Education to your organization – click here.

**Public Courses:**

We have a full schedule of public courses in the US, Asia and Europe in 2013. Click here for dates and locations to find one that is convenient for you!

**What our attendees are saying about CDISC courses:**
"The instructor was very knowledgeable and had a lot of personal experience with implementing ADaM so she was able to answer a lot of my questions. I liked the exercises - they really helped reinforce the material and gave us an opportunity to see how we might apply it to our work."

-ADaM 'In-House' Private Course on 18 July 2012

"The instructor was great in explaining the concept of SDTM. She seems very engaged in the subject which made the course much more interesting. She encouraged to ask questions. She was well aware which parts of SDTM that may be unclear and she focused on explaining them in details. I was happy with the course materials provided on a USB stick. It was easier to follow them on computer than browsing through the pile of paper."

-SDTM Public Course at European Interchange on 16-17 April 2012

"Showing the guidance and how to use it was very helpful. Having just had the STDM training the interrelationship between CDASH and STDM was particularly helpful."

-CDASH Public Course in Morrisville, NC on 23 Aug 2012

Stay tuned for more feedback from our loyal attendees and be one of them!

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PharmaSUG Conference on 12-15 May 2013 in Chicago, IL

Wayne Kubick, Chief Technical Officer of CDISC, will present the keynote address for this year’s PharmaSUG conference on the current state and future strategic direction of CDISC standards, and how they are evolving to meet the challenge of FDA’s PDUFA-V mandate for defining therapeutic area data standards.

Register for the conference through the following link [56] by 1 April 2013 to receive an early registration discount. And follow the link to know more about PharmaSUG [57].

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Early Bird Registration is now open for the FDA/PhUSE Computational Science Symposium, 17 – 19 March in Silver Spring, Maryland. Full details can be found here: http://www.phuse.eu/css [58]

The annual Computational Science Symposium will bring FDA, industry and academia together for updates and work on collaborations established at previous symposiums and continued throughout the year. Additional collaborative projects will be created to address the latest challenges relating to the access and review of data to support product development. The groups will work on possible solutions and practical implementations with the goal of helping the broader community align and share experiences to advance computational science.

CDISC Members are encouraged to join the working groups and to be part of these exciting developments as they move forward.


Exhibitor Opportunities http://www.phuse.eu/CSS-Exhibitors-2013.aspx [60]. Please follow the links for full details and contact PhUSE office@phuse.eu [61] for any further questions.

The Official CDISC Primer is available for a lower price [62].

Benefit from the discounted price and buy the CDISC book now! Current Price is $10 [63].

The CDISC Primer (Introducing the CDISC Standards / New Efficiencies for Medical Research) offers a detailed synopsis around everything you need to know to get started with the CDISC standards! Order yours today!

CDISC Social Media

Stay connected with the CDISC community through the CDISC social media. Join CDISC Facebook [64] and LinkedIn [65] and follow us on Twitter [66] and YouTube [67]. And follow our Blogs [68] and most recent News through our website [69]!
Further questions are welcome through the following email.

CDISC Communications and Public Relations

Source URL: http://www.cdisc.org/node/4436

Links:
[8] https://www.cvent.com/events/cdisca-2013/registration/d6c69ad960f34e687626a94f03761c35.aspx
[12] http://cdisc.wufoo.com/forms/7x1m7/
[18] mailto:prakhar@cdisc.org
[21] https://cdiscpm-sandbox.imedidata.net/
[27] http://www.painjournalonline.com/article/S0304-3999%2812%2900595-7/fulltext
[34] mailto:membership@cdisc.org
[35] http://www.cdisc.org/content3837
[36] mailto:sleaman@cdisc.org
[38] mailto:volunteer@cdisc.org
[43] http://www.cdisc.org/forms/2x7xk7/
[50] mailto:office@phuse.eu
[53] http://twitter.com/#!/CDISC
[54] http://www.youtube.com/user/CDISCric
[56] http://www.cdisc.org/groups/CDISC-56397
[57] http://www.cvent.com/events/cdisca-2013/registration/d6c69ad960f34e687626a94f03761c35.aspx
[59] http://twitter.com/#!/CDISC
[60] mailto:communications@cdisc.org