March 2013 Newsletter

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CDISC Europe Interchange 2013

- The CDISC Europe Interchange 2013 will be held on 22-26 April 2013 in Bad Nauheim, Frankfurt, Germany. Don’t miss out - register now! Our Interchange Keynote speaker, Dr. Michel Goldman, the head of the Innovative Medicines Initiative (IMI) will provide an overview on the State of the IMI Project.
- Frank Petavy of the European Medicines Agency (EMA) will present on the Clinical Data Transparency Initiative.
- Dr. Charles Cooper of the U.S. Food and Drug Administration (FDA) will present on the Challenges and Process in relation to Data Standards at FDA.

The conference will continue with presentations on the value of CDISC standards in streamlining clinical research and linking research with healthcare. There will also be a set of authorized CDISC educational courses offered on 22, 23 and 26 April: BRIDG Deep Dive, SDTM Theory and Application, ADaM Implementation, CDASH Implementation, Controlled Terminology and ODM Implementation courses will be offered during the Interchange week. Click here for more details on the courses offered.

Preliminary Program Available Here.

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

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.
Hotel Reservation

Don’t forget to make your hotel reservations through this link. Benefit from the CDISC discounted rate, please make sure to use the CDISC Discount Rate Code provided through the same link.

Bring Global Awareness to Your Organization and Sponsor 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.

In addition to featuring your organization through the CDISC various communication channels, sponsoring Interchanges can provide you various benefits; some of these benefits are as you see below:

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<th>Diamond Sponsor</th>
<th>Ripe Sponsors</th>
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<td>2 free booth spaces &amp; 4 conference passes including evening event. 2 additional evening event passes for clients. 4 pages advertisement in the conference bag. Logo and link on the event page of the CDISC website. Thank you in the CDISC newsletter. Signage where appropriate. Logo on conference program.</td>
<td>2 free booth spaces &amp; conference passes including evening event. 2 additional evening event passes for clients. 1 page advertisement in the conference bag. Logo and link on the event page of the CDISC website. Thank you in the CDISC newsletter.</td>
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Full details on sponsorship can be found here.

Extend Your Organization’s Global Reach and Exhibit at CDISC Interchanges

Expanding the visibility of your organization and meeting the top companies in healthcare is not limited with sponsoring at CDISC Interchanges! Exhibiting at CDISC events will provide your company the opportunity of interacting with key international organizations and global regulatory entities that will be attending the CDISC Interchange. Among the benefits of exhibiting is offering a free pass to the main conference, follow this link if you are interested in exhibiting at the CDISC Europe Interchange 2013.

Mark your calendars! The CDISC International Interchange will take place in Bethesda, MD on 4-8 November 2013. Information and further details will be coming soon; stay tuned to the CDISC website.

CDISC Press Release - CDISC Launches Learning Health Community Standards Initiative

The Clinical Data Interchange Standards Consortium (CDISC) organized and hosted a meeting in Austin, TX to launch the Essential Standards to Enable Learning (ESTEL) initiative of the Learning Health Community (LHC). The CDISC-led ESTEL initiative is the first of several that have grown out of the May 2012 Learning Health System (LHS) Summit, sponsored by the Joseph H. Kanter Family Foundation (KFF), which convened a critical mass of key stakeholders representing over 80 organizations across the healthcare spectrum and achieved multi-stakeholder consensus on a set of ten LHS Core Values that will underpin a national-scale LHS. Such consensus has given rise to the self-organizing (and ever-growing) Learning Health Community bonded together by a shared belief in the Core Values and a common drive to work collaboratively to transform healthcare and health by realizing an LHS. A key goal of a Learning Health System (LHS) is to significantly shorten the time by which clinical research results inform clinical care decisions to improve the lives of
CDISC Press Release - CDISC Announces Speakers from IMI, FDA and EMA for 10th Europe Interchange in Germany

Austin, TX – 11 March 2013 – The Clinical Data Interchange Standards Consortium (CDISC) is proud to announce the 10th CDISC Europe Interchange, to be held 22-26 April 2013 near Frankfurt, Germany. The conference, planned by the CDISC European Coordinating Committee (E3C), will include an all-star list of speakers.

The 2013 Europe Interchange Keynote will be delivered by Dr. Michel Goldman, head of the Innovative Medicines Initiative (IMI). Frank Petavy of the European Medicines Agency (EMA) will give a presentation on the Clinical Trial Transparency Initiative, and Dr. Charles Cooper of the U.S. Food and Drug Administration (FDA) will present on Data Standards in the FDA – Challenges and Processes. Additional Interchange speakers will represent TransCelerate Biopharma and CDISC members and standards adopters. “We are extremely pleased that experts will be presenting on behalf of FDA, EMA and IMI during this 10th CDISC European Interchange, which will be held in Bad Nauheim (near Frankfurt), where Elvis Presley spent two years of his life,” said Peter van Reusel, who chairs the E3C. “We can look forward to a very special evening event, for which our European Interchanges have become renowned.” Follow the link to read the full press release about the CDISC European Interchange.

DATATRAK CTO Elected as CDISC Advisory Board Chair-Elect

CLEVELAND [February 5] /PRNewswire/ — DATATRAK International, Inc. (OTCQX: DTRK), a leader in developing cloud-based, unified eClinical® technologies and delivering related services for the clinical trials industry, today announced Chris Wilke, DATATRAK’s Chief Technology Officer, was elected as the CDISC Advisory Board’s (CAB) Chair-Elect.

“We are very pleased to have Chris Wilke as a member of the CDISC Advisory Board’s leadership team. His many years of industry experience will add immense value to this group and will further promote our vision to inform patient care and safety through higher quality medical research,” said Dr. Rebecca Kush, President and CEO, CDISC. Follow the link for the full article.

CDISC Success Story

In an attempt to increase value for its stakeholders, CDISC initiated the feature of Success Stories in 2012, and we are continuing these in 2013. These stories reflect experiences with the CDISC standards and how they 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 topic is primarily focused on our success from the Asia-Pacific Interchange that occurred in February in Singapore.

Great Moments at the CDISC Asia-Pacific Interchange

The inaugural CDISC Asia-Pacific Interchange (CAPI), held in Singapore 18-22 February, was an incredibly successful event, drawing over 100 leaders from Thailand, India, Japan, Singapore, South Korea, China, and Australia, as well as the USA, France, the UK and Belgium. While conference content included traditional subjects, such as presentations on case studies using and implementing the CDISC standards, there were also heavily attended and engaging subjects specialized for the Asia-Pacific region. Specifically, there were updates on the status of clinical research and usage of CDISC standards around the Asia-Pacific region, region-specific presentations on the use of EHRs for research and a highly interesting session on therapeutic area standards, which included a presentation on the development of standards for traditional Chinese medicine (TCM).

There were many encouraging moments at CAPI, but one of the greatest highlights, to me, was the number of CDISC Board members that not only attended the bi-annual face-to-face Board of Directors meeting (held in Asia for the first time), but spent the rest of the week thoroughly engaged in the Interchange presentations and associated discussions. Eight CDISC Board members even took time out of their very hectic schedules to participate in a panel discussion and Q&A session for Interchange attendees. Follow the link for the full story.
**The CDISC Vision, Harmony, Chaords and a Learning Health Community**

The CDISC vision is informing patient care and safety through higher quality medical research. This might be viewed as the CDISC contribution to a 'Learning Health System'. When CDISC was founded in 1997, there was (and still is) a clear desire to streamline the means by which research information can be gleaned from clinical care to ultimately provide increasingly better knowledge to benefit patients. This desire was communicated as two key goals: 1) to make it easier for clinicians to do research, and 2) to improve data quality and patient safety.

You have heard this before, but we are all patients; and, those of us who have been working with CDISC for the past 1.5 decades are that much older and feeling an increased urgency towards accelerating the 'research-healthcare learning cycle'. The 17 years that it is said to take for research findings to make their way back into clinical care decisions is simply too long, and we all know that healthcare costs continue to skyrocket without the resultant improvement in speed of innovation nor quality of care. *Follow the link to read the full story.*

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**Join us for our monthly webinars to hear the latest updates and achievements on the CDISC standards.**

*Click here to view the scheduled webinars for 2013.*

Our most recent webinar "Learning Health System – Essential Standards to Enable Learning (ESTEL)" was scheduled on Thursday, 14 March 2013; CDISC members can view the recorded webinar on the Members Area of the CDISC website. For questions about accessing the recorded webcast, please contact Saad Yousef. The next webinar on the CDISC Standards - Latest Updates and Additions is scheduled on 11 April 2013 from 11:00 AM to 12:30 PM EST. *Click here for details.*

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**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.

CDISC has just posted an update to the SDTM/ADaM Pilot Submission package for use by CDISC members. The pilot package has been updated for consistency with current versions of SDTMIG v3.1.3, ADaM v1.1, and the ADaM IG.

In the coming weeks, CDISC expects to post the provisional user guide for Polycystic Kidney Disease v1.0 and Define-xml v2.0. Drafts to be issued for comment include the CV therapeutic area user guide the CDASH supplement for collecting Serious Adverse Event data consistent with ICH E2B.

We will soon be posting project team charters for 2013, beginning with the recently approved project charters for Asthma v1 and Alzheimer’s v1.1 therapeutic area standards. Asthma is the first CFAST project that directly involves TransCelerate Biopharma.

CDISC will also soon be posting a 2013 technical plan to with 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.*

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Follow the monthly column of our new CDISC CTO, Wayne Kubick, published in Applied Clinical Trials. Please see the latest on "Cutting Our Losses in Translation."
CDISC announces the Re-Launch of the ODM Certification Program!

CDISC began the ODM Certification program in 2007 with the intent of providing the industry/CDISC users, and companies offering ODM-capable products, the assurance that ODM files have a high level of conformity to the published specifications. Today, CDISC announces the re-launch of the ODM Certification Program with a new partner - Next Step Clinical Systems.

The Next Step Clinical Systems ODM Certification service is authorized by CDISC and will use a suite of updated certification tools capable of testing products against the latest ODM version requirements. Those passing this testing program will receive authorized CDISC Certification along with a number of other CDISC benefits, including more widespread communication of those who offer CDISC ODM Certified products.

Click here to learn more about the program, apply to become ODM Certified or to see the current list of ODM Certified products.

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:

How can you provide input to the CDISC standards?

First, follow our announcements and visit our website often to learn what new standards are accepting review comments and participate in these reviews. Second, participate in discussions on our Discussion Forum or via social media, such as LinkedIn groups. Join our working teams and gain access to the CDISC teams portals, please contact us at volunteer@cdisc.org if you would like to join a CDISC team. CDISC teams are volunteers who dedicate their time and effort to contribute to the CDISC standards and be part of the CDISC mission and vision. In addition, you can volunteer to our standards through this link, please fill out the form and submit to the email address listed on the top of form page. And if you would like to be informed about our latest achievements and updates, please join our mailing list through this link.

To get help implementing the CDISC standards, what should one do?

There are several different ways to reach out to the CDISC Community to receive assistance in implementing and utilizing the CDISC standards:

- Attend our education courses to learn how to implement the CDISC standards in your work environment. Follow these links to attend our private and public education courses at any location in the world.
- The CDISC LinkedIn Group is a fantastic way to not only ask questions about implementation of the CDISC standards, but also offers an opportunity to connect and engage your peers in the community. You can reach the CDISC LinkedIn Group through this link.
- Join a CDISC user network in your region. See the FAQ on our user networks for more information.
- The CDISC Discussion Forum (under Resources on the CDISC website) is another way to reach out with questions regarding the standards, and you can get assistance with your questions from staff, volunteers that worked to develop the standards, and from veteran users of the standards. You can reach the CDISC Discussion Forum through this link.
- Should you need assistance in implementation that has not been addressed on one of our forums, or should you like to reach out to someone directly with your questions, please contact us at info@cdisc.org. We will connect you with the right individual to help you.

How Does CDISC Communicate?

The following are the CDISC communication channels through which we connect with our members and non-members. Please make sure to join our mailing list to get the most current information.

1. You can also join our mailing list on the CDISC homepage through the following link: Join Our E-mail List to receive latest information on our standards, events and education courses.

2. The CDISC Members Area of the website also includes tools and new information available to those who join CDISC (see this link to find out if your company is a member and, if not, see this link to view the benefits of becoming a Member).
CDISC Newsletter: It is issued on a monthly basis and can be accessed through the CDISC homepage.

CDISC Social Media: (LinkedIn, Twitter, YouTube and Facebook)

CDISC Blogs: click here to see all blogs.

CDISC Announcements (e.g. Technical Updates and opportunities to attend CDISC webinars and events). Join our mailing list to receive these updates constantly.

CDISC Press Releases: They can be viewed through the following link.

CDISC Journal Articles

CDISC Annual Report: The APR can be accessed through the CDISC website.

CDISC Advisory Council teleconferences: available to representatives of the CDISC Platinum Member Organizations. If you are a CDISC Platinum Member representative and would like to join the CAB teleconferences, please contact Sheila Leaman.

CDISC Standards Update webinars.

CDISC Educational courses. We offer public and private education courses.

RSS Feed: Subscribe through this RSS Feed to know about what is new. And subscribe to this RSS Feed to know about the latest updates on our standards.

And most importantly, CDISC Interchanges: Interchanges provide a great opportunity to learn about our global achievements and latest updates. Click here to know more about our interchanges and events.

What is a CDISC User Network? Who are they? Where are they?

CDISC User Networks enable face-to-face interactions in specific regions or languages, depending on the region. They are self-formed groups that encourage the adoption and understanding of the usefulness and value of CDISC standards.

The purpose and benefits of CDISC User Networks are to:

- Share CDISC implementation experiences periodically in a given region or language
- Discuss draft standards and comments to CDISC
- Discuss mature standards and feedback to CDISC on usefulness
- Discuss new ideas to be channeled into CDISC
- Network among colleagues
- Share recent conference participation and learning

User networks represent CDISC in China, Japan, Europe (French-speaking, English-speaking and German-speaking), and in ten areas of the United States [Bay Area, CA; Boston (BACUN); Atlantic region (CT, NJ, NY); San Diego; Midwest; Delaware Valley; Raleigh-Durham; Heartland; Seattle, Washington DC (DCDISC)].

For further details on CDISC User Networks, please follow this link to review the CDISC Operating Procedure on User Networks.

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

Click here for more details on our FAQs.

CDISC Members Updates

Our New Members in February

New Gold Members in February:

- R-Square, Inc.
- CSL Behring

Thank you and a warm welcome to our new members in February. 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.

Thank you to CDISC STAR Members

Star Members in February:
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.

Boston Area CDISC User Network (BACUN) is planning its next user network meeting on 8 May 2013 from 11:00 AM to 1:15 PM at Vertex in Cambridge, MA.

Join the Boston Area User Network for lunch, networking, and a discussion about ADaM implementation. To receive BACUN meeting announcements directly, subscribe to the BACUN Yahoo Group ‘BostonCDISC’, or send a request to join the mailing list to melissa.k.cook@accenture.com.

Two recent CDISC Japan User Group (CJUG) meetings took place this month:

On Friday, 8 March 2013, an SDTM team meeting was hosted by CJUG at ASKLEP Inc., Akihabara Office in Tokyo, Japan where 32 team members attended. The schedule was full with presentations and recent updates:

1. The first session started with an online presentation on “Managing Data Quality and Standards Compliance with OpenCDISC,” by Max Kanevsky from OpenCDISC/PINNACLE21. Click here for photos from this meeting. The second session was about SDTM Implementation and further actions. The third session concluded the meeting with a presentation on “About PhUSE” by Mr. Hajime SHIMIZU, Takeda Pharmaceutical Company Limited.

2. Another CDISC Japan User Group (CJUG) Workshop took place on Tuesday, 12 March 2013 from 10:30 to 17:30 at CAC EXICARE. The 3rd page on the following program displays the English version of the schedule. The workshop presented the CDISC Japan User Group latest updates and activities.

CJUG workshops are scheduled to be held yearly during the spring. Last year it was held on 27 March 2012. CJUG members attended to discuss and exchange their latest experiences and to provide presentations on the recent CJUG team activities. And, as in previous years, CJUG members get together for a nice warm networking event to network and...
chat with colleagues after the workshop is completed. The purpose of these CJUG workshops is to exchange information and share experiences among team members. The CJUG plays an essential role in spreading the knowledge about CDISC in Japan. They share CDISC experiences and communicate the latest achievements about the CDISC standards in their regions.

Future User Group Meetings in Japan:

The next SDTM Team meeting will be held on 12 April 2013 at Dainippon Sumitomo Pharma Co., Ltd. The meeting is scheduled from 12:45 to 17:00 where the following topics will be discussed:

1. Online presentation: “About PHUSE” by Mr. Senk Frank from 13:00 to 14:00, Japan time.
2. Presentation on “SDTM Filesize Issue Updates” By LiSaS, Mr. Yasutaka MORIGUCHI, Santen Pharmaceutical Co.

In addition, an SDTM Data Implementation Activity sub-group meeting will be held to discuss the following:

1. Create CRF sub-sub-group
2. Create Trial Design Model group
3. EDC Builder sub-group
4. Protocol sub-group

Furthermore, the SDTM team scheduled an external invitation for the following presentation topics:

1. Presentation on the “Challenge of linking EHR to EDC” at Kagawa University Hospital on 10 May 2013.
2. “About next eCTD” by Mr. Ohbayashi at Meta-cube on 14 June 2013.
3. Another presentation will be held at the MHLW (Ministry of Health, Labor and Welfare) Office of Clinical Trial Promotion Research and Development Division Health Policy Bureau on 12 July 2013.

To join a CDISC User Network, contact Diana Harakeh[16]. The User Network portal area[49] is open to anyone and provides information on specific User Networks, including announcements of their next meetings.

Follow the link[6] to know more about the purpose and benefits of the CDISC User Networks.

Donate to CDISC[6]

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[6] to know more about how to make your valuable donation.

CDISC Standards Need Volunteers Like You[7]

CDISC relies on volunteers to develop and improve data standards products. The best way to get involved is to download and use CDISC standards, and to participate as a reviewer of new standards posted for comment on our website.

The following CDISC teams are also currently looking for new participants:

- XML Afficionados
- Protocol Representation
- Terminology

Follow the link[7] to know more about how to volunteer! Further questions, please email us here[28].

Also stay tuned for an upcoming webinar where we will describe how to get more actively involved in CFAST Therapeutic Area Data Standards project teams. Details on our webinars can be found here[17].
CDISC Global Events and Education Opportunities

CDISC Interchanges:
- CDISC Europe Interchange in Germany, 22 - 26 April 2013. Offline and Online Registration are Available. 
- CDISC International Interchange in North Bethesda, MD, 3 - 8 November 2013. Registration and details will be available soon.

Join us for our monthly webinars to hear the latest updates and achievements on the CDISC standards. Click here to view the scheduled webinars for 2013.

Our most recent webinar “Learning Health System – Essential Standards to Enable Learning (ESTEL)” was scheduled on Thursday, 14 March 2013; CDISC members can view the recorded webinar on the Members Area of the CDISC website. For questions about accessing the recorded webcast, please contact Saad Yousef. The next webinar on the CDISC Standards - Latest Updates and Additions is scheduled on 11 April 2013 from 11:00 AM to 12:30 PM EST. Click here for details.

Upcoming Public Course Offerings

Are you interested in the CDISC Public Courses offered in South San Francisco, CA from 6 to 8 March 2013? Contact Saad Yousef for more details.

CDISC EU Interchange in Frankfurt, Germany

Courses Offered:
- SDTM Theory and Application (22-23 April)
- BRIDG Deep Dive (22 April)
- ADaM Implementation Model (23 April)
- CDASH Implementation (26 April)
- ODM Implementation (26 April)
- Controlled Terminology (26 April)

Click here to register.

CDISC Public Course Offering in St. Louis, MO

Courses Offered:
- SDTM Theory and Application (21-22 May)
- CDASH Implementation (23 May)
- ADaM Implementation (24 May)

Click here to register.

Discount period ends 28 February.

CDISC Public Course Offering in Audubon, PA

Courses Offered:
- SDTM Theory and Application (4-5 June)
- CDASH Implementation (6 June)
- ADaM Implementation (7 June)

Click here to register.

Discount period ends 4 March.

All other public course offerings in US, Asia, and Europe can be found by clicking on the following link.

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.

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!

The Official CDISC Primer is available for a lower price [8]

Benefit from the discounted price and buy the CDISC book now! Current Price is $10 [8].

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 [8] and LinkedIn [8] and follow us on Twitter [8] and YouTube [8]. And follow our Blogs [8] and most recent News through our website [8]!

Further questions are welcome through the following email [64].

CDISC Communications and Public Relations [64]