

NINDS Confidential  
**Meeting Summary**  
**NINDS Common Data Elements**

**Steering Committee**  
**Monday, September 21, 2015, 12:00 p.m. Eastern Time**

**Participants**

Steering Committee:	Lucie Bruijn (Chair), Nicholas Barbaro, Mitchell Brin, Gary Cutter, Thomas DeGraba, Jordan Elm, Jacqueline French, Laurie Gutmann, David Loring, Fred Lublin, David Lynch, Richard Moxley, Yuko Palesch, Ralph Sacco, Jeffrey Saver, Ira Shoulson, Caroline Tanner Virginia Howard (attended call on 9/14/15)
Advisors/Consultants:	Alison Garcia, Bron Kisler, Michael Lawlor, Matthew McAuliffe, Christian Perez, Dianne Reeves
NINDS:	Patrick Bellgowan, Brandy Fureman, Lyn Jakeman, Scott Janis, Joanne Odenkirchen, Ursula Utz
EMMES:	Muniza Sheikh, Robin Feldman

		Summary of Action Items/Discussion
1.	Action Items	<ul style="list-style-type: none"> <li>• The Steering Committee (SC) appeared in agreement that the education year count CDE should be moved from General Core to Supplemental – Highly Recommended (S-HR) classification.</li> <li>• The SC agrees that additional work is needed on the General Neurological Exam. Please send any comments or revisions to Ms Odenkirchen and <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> <li>• The General Demographics form will be kept specific to TBI. Please send any comments to Ms Odenkirchen and <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> <li>• Slides on the CDISC/CFAST Therapeutic Area Program were sent following the meeting. Please email <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a> or Mr. Kisler at <a href="mailto:bkisler@cdisc.org">bkisler@cdisc.org</a> if you have any questions.</li> <li>• The SC was in agreement on the new terms of membership with a three-year limit and one-quarter of members being rotated off. If anyone would like to be rotated off, please contact Ms. Odenkirchen and <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> <li>• Feedback on the NINDS CDE website, the new tutorial or any other comments should be sent to <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> </ul>
2.	Discussion	<p><u>Opening Remarks</u></p> <ul style="list-style-type: none"> <li>• Dr. Bruijn welcomed all to the meeting and stressed the importance of continued renewal and revision of the CDEs.</li> <li>• Ms. Odenkirchen mentioned that the aim is to generalize CDEs throughout NINDS and put them out for the larger community to use. There is also a paper being written at NIH on the overall CDE effort that will be complete next year.</li> </ul>

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	<p><u>Updates since Previous Meeting</u></p> <ul style="list-style-type: none"> <li>• Ms. Odenkirchen provided an update on the 18 disease areas, including the newest diseases posted to the NINDS CDE website since the last meeting: spinal cord injury (SCI), mitochondrial disease (Mito) and three new neuromuscular diseases (congenital muscular dystrophy, myotonic dystrophy and Facioscapulohumeral dystrophy).</li> <li>• The posted disease areas are undergoing minor QC changes right now, and the three new NMD diseases as well as Mito are working on publications.</li> <li>• Disease areas underwent revisions to their Core classifications over the last year, which were revised to Supplemental – Highly Recommended or Supplemental.</li> <li>• The Headache CDEs will be reviewed over the next year to reduce the number of Core under the leadership of Dr. Oshinsky as Program Director. Ms. Odenkirchen thanked Dr. Brin for his input during the last meeting.</li> <li>• SCI-Pediatric CDEs are in development and will be posted to the website for public comment this Fall. An Oversight Committee has also reviewed the current recommendations and their revisions will be posted early next year. We will continue to work with the American Spinal Injury Association (ASIA) and International Spinal Cord Society (ISCoS) in maintaining the SCI CDEs.</li> <li>• Traumatic Brain Injury (TBI) CDE update: we are planning on making sports concussion and blast sensory CDEs in the near future and will continue to work with Clinical Data Interchange Standards Consortium (CDISC) to harmonize the TBI CDEs.</li> <li>• Special CDE Activity: Newer CDEs are being developed through the National Library of Medicine (NLM) repository pilot project, which uses the same process and the new CDEs will be posted on the NINDS CDE website for public comment: <ul style="list-style-type: none"> <li>○ Chiari Malformation (CM), cerebral palsy (CP), subarachnoid hemorrhage (SAH) and unruptured aneurysm</li> </ul> </li> <li>• Vision for CDEs is that all future NINDS-funded trials will use the CDEs or be CDE compatible.</li> <li>• Dr. Brin suggested that having a way to demonstrate the use of CDEs in clinical trials (e.g. via a bar graph) would be a good way to showcase their usefulness. He stressed that their implementation is an important milestone and if we can show CDEs being used, what phase they're in and whether they helpful in the trials, it would be very useful feedback.</li> <li>• Dr. Barbaro expressed concern over the request for public comment for newly posted diseases. He would like to make sure we are getting this request to the larger societies such as the American Academy of Neurology (AAN), which can then distribute to the smaller groups.</li> </ul> <p><u>Supplemental – Highly Recommended Classification</u></p> <ul style="list-style-type: none"> <li>• Ms. Odenkirchen explained the need for a Supplemental – Highly Recommended classification as clinical trials were being overwhelmed by too many required Core CDEs.</li> <li>• Dr. Saver described the process of how the stroke CDEs were revised in a three-dimensional format based on study type, disease stage and disease type. This was</li> </ul>

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	<p>presented via the revised Stroke Start-Up Resources document.</p> <p><u>Revisions to General Core CDEs discussion</u></p> <ul style="list-style-type: none"> <li>• Dr. Saver introduced the idea that the Stroke group would like to move the education year count CDE to Supplemental – Highly Recommended (S-HR), as this would give more flexibility to researchers.</li> <li>• Ms. Odenkirchen explained that the education year count CDE was developed because it was the easiest method of collecting education information over the age of five internationally, and then opened the discussion for comments: <ul style="list-style-type: none"> <li>○ Reasons given to keep it as Core were that it is easy to complete and highly relevant as a marker for cognition and socioeconomic status</li> <li>○ Reasons to move it to S–HR include that it is difficult to characterize different types of education and difficult to classify different types of education in certain regions. If changed, it will most often still be collected, just not required, which will reduce financial burden.</li> </ul> </li> <li>• The SC agreed to move the education year count CDE to S-HR</li> </ul> <p><u>General Neurological Exam Form discussion</u></p> <ul style="list-style-type: none"> <li>• Ms. Odenkirchen asked the SC whether the exam is useful and if there is anything missing.</li> <li>• Dr. Gutmann expressed concern that the exam is not intuitive to how we collect information and needs revision. She also asked if the exam is to be used as a template, or for those who don't normally perform neurological exams.</li> <li>• Dr. Shoulson stated that the exam is useful but does require ongoing revision.</li> <li>• Dr. Sacco agreed with its usefulness and said that it would definitely need more work.</li> <li>• The SC agreed that the exam should be performed by a trained professional, and this should be stated on the form.</li> <li>• Dr. Elm expressed concern over the over-collection of data, which could be costly.</li> <li>• Ms. Odenkirchen agreed that the form needs more work and additional comments are welcome. Please send any comments or revisions to <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> </ul> <p><u>General Demographic Form discussion</u></p> <ul style="list-style-type: none"> <li>• Ms. Garcia explained that the form was developed by the Federal Interagency TBI Research (FITBIR) Informatics System operations team, which looked at both demographics forms across NINDS and those received from FITBIR studies. It is a comprehensive form designed to fill in the gaps that have been found.</li> <li>• Ms. Odenkirchen asked the SC if the form is too generic, or too specific to TBI.</li> <li>• There were questions on the Global Unique Identifier (GUID), which is specific to TBI and the only required element on the first page.</li> <li>• There was also concern over why the form is needed, since there are already general Core elements.</li> <li>• Ms. Odenkirchen explained that this form would not be required and investigators can choose which elements to collect. She asked whether the form would be a good</li> </ul>

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	<p>idea to have as a general form, or should it be kept specific to TBI and requested feedback within two weeks.</p> <p><u>Update on CDISC/CFAST Therapeutic Area Program</u></p> <ul style="list-style-type: none"> <li>• Mr. Kisler gave an update on Coalition for Accelerating Standards and Therapies (CFAST) program:               <ul style="list-style-type: none"> <li>○ CFAST initiative is a structure designed to prioritize the requests for the therapeutic areas (TA) CDISC was receiving.</li> <li>○ Therapeutic Area Data Standards User Guide for Traumatic Brain Injury (TAUG-TBI), which involves acute TBI in adults, underwent public review ending on September 21, 2015. The final version will be posted December 2015.</li> <li>○ Dr. Saver asked about changes to current NINDS CDEs that may come about as a result of CFAST. Ms. Odenkirchen explained that it would depend on the question and the reason the particular CDE is being collected. Some issues may need to be addressed by the original WG.</li> </ul> </li> <li>• Mr. Kisler also described the new Shared Health and Research Electronic Library (SHARE), which is a global electronic repository. In 2016 the aim is to develop all therapeutic areas through SHARE, which will accelerate their development. SHARE will be available to academic researchers in early 2016.</li> </ul> <p><u>Terms for Steering Committee Members Discussion</u></p> <ul style="list-style-type: none"> <li>• Ms. Odenkirchen proposed the idea of having a three-year term limit for SC members, with one-quarter of the membership being rotated off. This will add additional international membership to some disease areas, as well as a new perspective to the Committee. The SC was in agreement with this plan. If anyone would like to be rotated off, please contact <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> </ul> <p><u>Publications and Presentations</u></p> <ul style="list-style-type: none"> <li>• A listing of publications and presentations was provided with meeting materials. Please send any comments to <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a> for any revisions.</li> </ul> <p><u>Website Feedback</u></p> <ul style="list-style-type: none"> <li>• A new website tutorial was also sent with meeting materials. Please send any comments to <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> <li>• Comments on NINDS CDE website: Please review your disease areas as well as the website in general. If you have any comments or would like a tutorial, please contact <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a>.</li> </ul> <p><u>General Comments</u></p> <ul style="list-style-type: none"> <li>• The NINDS CDE Team will be at the upcoming American Epilepsy Society (AES), International Stroke Conference (ISC) and American Academy of Neurology (AAN) meetings at the NINDS booth to provide tutorials on the website.</li> <li>• Please send all feedback to <a href="mailto:NINDSCDE@emmes.com">NINDSCDE@emmes.com</a> and Joanne Odenkirchen.</li> </ul>