



March 25, 2019

Dear Trauma Registry Stakeholders:

We are providing this joint communication from Clinical Data Management (CDM), Digital Innovation (DI), Lancet Technology (Lancet) – collectively the “Trauma Registry Vendors” and Analytic Solutions Network (ASN) to give you the latest update on 2019 compliance changes. As you hopefully know, ACS has been making advancements to its Quality Programs, ACS TQIP®, which now appear to be fully implemented. The May 2019 deadline for submission in the new ACS/IQVIA technical NTDS XML format is now upon us all. This transition is by far the most significant technical transition that has ever occurred in our history, given its scope and timeframes and has profoundly affected ACS, Vendors, Trauma Centers, States and Systems. The impact of this change is and will continue to be felt by everyone. The 2019 transition to new technical requirements is not “business as usual” which has become clear to most of you in the last few months.

We recently received information that another revision to the software development kit (SDK) will be required by May and that ACS and IQVIA are currently preparing that update for a release in the coming weeks. This additional update means that we will need a solution to connect the entire country to this update, and tools to allow you to revalidate your Q1 data.

Fortunately, the centralized approach afforded by the ASN Compliance Hub allows for a nationwide deployment that otherwise might not be feasible in the timeframes required. The need for rapid wide-scale deployment is a principal reason ASN was created -- to allow implementation of critical changes in the most time efficient manner. The importance of a centralized approach could not be more evident as 2019 unfolds. The time it would take to update thousands of computers, run by over 2,000 IT departments nationwide, to this latest validator patch would be overwhelming. Fortunately, ASN anticipated and prepared for this reality by implementing a single point of maintenance for centralized data validation. Those of you who have completed your paperwork for the ASN Compliance Hub will be connected to the new Validator nationwide within days of its release. The value this provides is state of the art and ASN is excited and proud to be able to support this functionality.

We realize there are many questions related to this transition overall. These are exciting but changing times in our industry and we recognize change can be difficult. We have been transparent throughout this process in the form of numerous communications that shared each new piece of information that was available to us. Keep in mind that until early November 2018 we did not have all the information or SDK's that were needed to do a full national rollout or determine potential options to the ASN centralized approach.

To stay connected for national compliance, there are actions you need to take NOW.

We have several options independently and collaboratively described in Appendix 1 that will ensure you can remain compliant, but also allow you to receive enhanced real-time data validation and analytic capability integrated directly within your trauma registry software. We have built the technical foundation to prepare and support your organization for future significant changes and challenges likely to come in 2020 and beyond, as our industry progresses towards real-time PI requirements. We have collaborated to provide free industry tools through the Trauma Vendor Alliance (TVA), a public benefit



company, to help drive innovation and efficiency. We have collaborated to develop an infrastructure to provide options for efficiency that no single company could provide on its own due to the size, scope and scale of the ACS changes. All ASN offerings are available to all interested centers, vendors, and products including all independent offerings of the Trauma Registry Vendors ensuring your ability to choose freely regarding what local software solution you wish to use to meet programmatic and compliance needs.

Working together through open and transparent communication(s) is the only way to make this transition as smooth as possible. As a vendor community, we are committed to doing just that, while working collaboratively with ACS and any other organization.

Our goals are:

- to innovate and streamline the data validation, data submission, and PI process on a national scale
- to facilitate the participation of trauma centers using any trauma registry software they choose, and to participate in any risk adjusted database that they choose to meet ACS requirements, now and in the future.

Our focus now is on the present. The 2019 ACS SDK that is required for TQIP submission and data validation is still in progress by ACS and IQVIA, due to a critical fix we were just alerted to as of 3/13/19. This update to the SDK is on top of several other releases of the Validator and SDK that have occurred since November, including two in February.

We realize that change of this nature takes time and applaud ACS for driving our industry ahead with clinical and PI innovations. These types of unplanned changes are to be expected with a switchover to new a technical platform. The ongoing refinements are precisely why ASN was created– so the Trauma Registry Vendors could move quickly when the unexpected occurs and move efficiently and innovatively when the expected occurs.

Collectively, we now know everything that is required and relevant for 2019 and time is of the essence. If you have not done so already, it is imperative you register with the Trauma Cloud™ and consider your participation options with the ASN Compliance Hub as described in Appendix 1. Over 1,000 centers and systems have completed registration. Registration with the Trauma Cloud™ entails no patient data submission, it is merely a process of assigning a unique ID # to your facility for tracking purposes. Each of the Trauma Registry Vendors has also been working on contingency plans to give you more time to consider and implement your options. You should not delay since the stopgap interim solutions will be temporary and not ideal from a registrar workflow standpoint. But rest assured you will be able to submit your data.

Our vision is one of all trauma registries and quality programs to operate interconnectedly. Consequently, trauma registry data can flow to regional and state PI systems for real-time analytics, and then automatically to national PI databases with no extra steps allowing for national and state benchmarking at every level of aggregation: hospital, hospital system, regional, state, national.

The vision of ASN and its risk adjusted benchmarking potential is not at odds with participation in ACS TQIP® or any other repository. We encourage all centers to be in all relevant PI databases that they find of value and believe that participation in several PI databases is the wave of the future. We are innovating



to make that possible with essentially no additional work or data submission, and in many cases, at no or minimal additional cost.

Simply stated we are innovators that seek to make your use of our products better, and to bring about solutions that are bigger than those that can be done by the Trauma Registry Vendors, ACS, or any other organization alone. We are excited to be part of this journey with you. Now that you have seen more of the big picture and challenges that we face, and the value that ASN adds, you can better see how our passion and planning over the past 2 years comes together to support you, ACS, and most importantly, the injured patient.

Sincerely,

Your Trusted Trauma Registry Partners

Jody Summers
Clinical Data Management

John F. Kutcher, Ph.D.
Digital Innovation, Inc.

Leon Bowman
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Sue Auerbach
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APPENDIX 1

ASN Compliance Hub Options

A centralized approach is critical to ensuring you can receive up to the minute Validator revisions, but just as important, is also essential for supporting real-time analytics to enhance quality of data and ultimately quality of care. The ASN Compliance Hub provides a centralized solution critical to this modern age of rapid change and increasing PI and data quality.

Only your current vendor can offer real-time integration to existing registries (such as those from CDM, DI, and Lancet). ASN and the Trauma Registry Vendors are eager to help your system improve PI. ASN is open to participation by any interested vendor or center regardless of registry product, that uses open TVA standards.

To best serve your needs there are several ASN Compliance Hub options available. Since the compliance solution is based on ACS and TVA industry standards, this is an area where additional independent offerings would offer no time or cost advantage to develop or offer. We would only be reinventing the same wheel, and in times like these, efficiency and trauma center value is paramount.

The ASN system will revalidate all of your Q1 submissions giving you real-time dashboards to assist you in getting your data clean by the June 2019 deadline. As you can see, these tools and these approaches are invaluable to data quality and registrar productivity. The ASN Compliance Hub allows the Validation to be updated rapidly, with national access, because of the centralized approach.

Subscription Option - ASN has offered its services for the ASN Compliance Hub under a subscription service for a low \$1,750 annual fee (which is less than \$5/day) and a one-time setup fee (\$2,000) for TQIP centers. The ASN Compliance Hub is not only cost effective but it is innovative.

All of the Trauma Registry Vendors products will have real-time connections to the ASN Compliance Hub giving you “in-record” validation to the latest ACS IQVIA Validator with a visual dashboard powered by Driller®, a visual analytics tool. This allows you to see your validation across an entire year or quarter of data in a graphical display that allows you to drill down only into your center’s individual patient data. In-record validation is being finalized for a Summer delivery, since our current focus is on ensuring national compliance deadlines.

Note that a subscription to the ASN Compliance Hub does not entail any data sharing. Your data is used only for your facility’s data validation and data submission. The data resides securely on Microsoft Azure servers (some of the most secure in the world and typically far beyond any hospital IT security environment). This secure data retention allows for the revalidation of your data as new Validator releases occur, such as the one that will be released in May.

Private Install Option - The ASN Compliance Hub is also available for private installations on health system, regional, county, or state servers for an additional single system-wide support fee. This fee is in addition to the per center subscription options above; and includes support by your vendor of choice to update the servers as new patches and updates are released. This option allows your organization to



receive the benefits of the centralized approach and the innovation of Driller® with all data residing in your infrastructure.

As you can imagine, such a Hub can also pave the way to turn your State, RAC, or Hospital System registry into a real-time PI tool, with your own local copy of your centers' TQIP database for your own research, PI, and collaboratives.

Free ASN Compliance Hub Option - We recommend and encourage all centers to participate in the base ASN Compliance Hub solution. This free option is available to all trauma centers and requires a Data Use Agreement (DUA). The DUA is intended and designed to be no more and no less than what is prescribed in ACS CD 15-5 requirements. You can view more information by visiting the ACS website or www.StandUpForPI.org. Please know ASN will not share or provide access to your data to any 3rd party. Our interest is in helping to support ACS requirements for risk adjustment and CD 15-5.

ASN will use our team to develop risk adjusted models that we will freely publish and donate to our industry, including for free use by ACS TQIP® if desired. We are doing this in part to carry on the legacy of Dr. William J. Sacco, a mentor of DI's CEO who established a non-profit Foundation to carry on his work and legacy upon his passing. Dr. Sacco was a co-inventor of our industry's first risk adjusted model, TRISS, which is still used to this day. ASN has been developing newer models and will continue to modernize his work -- aligning it with modern data and establishing the associated norms for highly improved modern trauma care. ASN will also generalize this statistical risk adjustment work to support additional cohorts. This altruistic goal is part of us giving back to our industry in support of our nation's Zero Preventable Death initiative.

Nearly 200 centers have already completed the participation process in the full ASN offering. These are exciting times of innovation. All state and regional systems, or collaboratives, that utilize the ASN Compliance Hub can work with the TVA to implement a free PI pilot project. By working together, we can do more, and give your system better access to your centers' data for centralized analysis by your stakeholders. Our vision is to create an end-to-end real-time PI system.



APPENDIX 2

ITDX Background

What sets ASN apart is that it works in real-time with your trauma registry! Your participation in ACS TQIP® can benefit from this type of tight integration with trauma registry products.

This interoperability between vendors and systems is made possible by the ITDX. ITDX is the vendor's "new name" for the same technical XML data standard that was developed by DI for ACS at the introduction of NTDS in 2009 to support ACS clinical requirements. ACS presently no longer elects to have the vendors provide the XML designs for the exports we must produce, and at present, does not accept the XML format that the Trauma Registry Vendor products produce. It took the Trauma Registry Vendors a decade to perfect the existing technical approaches from 2009-2017, making our decision to continue with this proven approach an easy one to make. A "Convertor" is required from ITDX to NTDS for any state or regional repository that elects to not support ITDX. (This is another reason for a centralized approach and the ASN Compliance Hub).

Fortunately, we did not abandon our technical XML work in support of ACS's clinical standards when ACS made its transition in 2017 to a new platform. At the expense of the Trauma Registry Vendors, we came together via the Trauma Vendor Alliance (TVA) to donate our time and services to our industry as a public benefit corporation. We have continued to maintain the XML and to keep the ITDX XML 100% harmonized with the clinical revisions of each annual ACS NTDS Data Dictionary Release. We are already working on ITDX 2020. We invite any interested vendors, State, and ACS to participate in our ITDX workgroups. All ITDX standards are free and available for everyone.

ITDX allows trauma registries to connect to centralized databases needed for compliance or PI. The majority of US States that had previously used the DI NTDS XML format as a technical foundation are in the process of transitioning to the ITDX technical format, as are large national healthcare organizations and systems.

In short, ITDX is everywhere. In fact, ITDX has been developed and built into every product offered by the Trauma Registry Vendors without additional charge to the users. Read more about ITDX and download the 2019 ITDX Data Dictionary at www.TraumaVendorAlliance.org.

We hope that ITDX will eventually be supported by all quality programs and databases. This will help further streamline processes and reduce costs. In fact, any system or national quality program that supports ITDX will work with all of your software without change! We hope ACS will consider this approach in the future and would offer our services to assist.

TVA developed ITDX to help with standardized data collection for states, systems, and national repositories. The TVA made ITDX freely available to any interested system, vendor, association, university, or college. The importance of centralization to innovation and registrar efficiency remains paramount. As such, our recommendation is for you to subscribe to the ASN Compliance Hub.

APPENDIX 3

ASN Compliance Hub

The ASN Compliance Hub provides a centralized solution that allows your local trauma registry to “stay connected” to ACS quality programs.

The ASN Compliance Hub and its components play an important role in helping you meet the requirements for data submission and getting your trauma center ready now (with enhanced tools for supporting data quality and registrar productivity), and better prepared for the future.

