June 5, 2017

Dear Valued Trauma Registry Users and Stakeholders,

As trauma registry vendors, we wanted to make you aware of transitions that are occurring in the industry that could have a far-reaching impact on your trauma center. As you have undoubtedly seen, the ACS has recently sent correspondence regarding changes and transitions related to TQIP and NTDB submissions. As 98% of all TQIP centers (based on a TVA Survey conducted in September of 2016) utilize either Clinical Data Management (CDM), Digital Innovation (DI) or Lancet Technology, we have decided, acting collectively in support of free industry initiatives of the Trauma Vendor Alliance (TVA), to contact you jointly to discuss our plans to support you as our clients.

We believe that the planned ACS transition could be one of the most impacting events to us and you in trauma software history. We realize that most of you have no idea of the amount of work that we, as your vendors, have been doing behind the scenes for the past 13 years to keep you in lockstep with the ever-changing compliance requirements of ACS. However, since the relaunch of NTDB that we helped fuel with our software engineering and support efforts, our collaboration with each other and ACS helped establish a national infrastructure that allows your data to move to ACS NTDB and ACS TQIP® databases seamlessly and cost effectively.

We are writing to you because as the ACS is making changes, it is important to understand that we are the only organizations that can design, modify, and update our software. More importantly, any changes and cost bearing impact of any of the ACS's business decisions on our software will fall directly on our users and us. Therefore, we must now make you aware of the many details that are necessary to support our users, and we need your help to allow us to guide you through this transition.

Over the past 18 months, we have been making significant investments in preparation for the July 1st transition. Additionally, we have reached out to ACS and QuintilesIMS on numerous occasions to coordinate and plan this transition (well in advance of it) in collaboration with us. Unfortunately, the transition is now 25 days away and we have been unable to collaborate with them on the transition. Thus, as of today, there is much that we do not know related to the ACS's transition plans. However, there is also much that we do know. Please take the time to read the attached correspondence which outlines this information and our strong recommendations for what you, as our valued clients and stakeholders, should do to navigate this transition.

Over the past 13 years, we have independently invested millions of dollars in our respective software systems to help support your participation in ACS NTDB and ACS TQIP®. The specter of modifying any of the existing software over the next 25 days, let alone making any major architectural transitions over the next 6 months is, in our opinion, unreasonable and impractical. None of our companies are receiving any funding from ACS as of July 1 to perform these functions, yet we all could have a significant amount of work to do. We have engaged in many initiatives and provided services to the industry without charge to help you prepare for this transition. We need you and your leadership to support our technology contributions to you to minimize the financial impact on your trauma center(s).

What to do next?

- If you are a Hospital using CDM, DI, or Lancet - you should continue to have us use the **Vendor Validator™**. See attachment for details.
- If you are a Hospital using different registry software, you can still register for a free **Vendor Validator™**. See attachment for details.
- If you are a State, Region, or System and have adopted the NTDS standards in whole or in part, you should adopt **ITDX** as your "base submission format" for remaining harmonized with NTDS to meet NTDB 2018 compliance requirements. See attachment for details.

Stay tuned for more updates and announcements. **For now, you should just register at www.TraumaCloud.com by July 1, 2017.** We, as your trusted vendors and business partners, have steered you well for over 30 years. With our combined 90+ years of experience we are asking you to accept free software (namely, the free Vendor Validator and ITDX) and associated support from us. We are making significant investments in technology to help you improve outcomes, save lives, and most importantly, help buffer you and us from unexpected cost impacts outside our control.

Sincerely,

Jody Summers	John F. Kutcher, Ph.D.	Leon Bowman
Clinical Data Management	Digital Innovation, Inc.	Lancet Technology

JOINT VENDOR LETTER

ACS Transition Details as of June 1, 2017

It is helpful for you to first understand how your data gets from your registry software to NTDB and ACS TQIP®. Your data is transmitted to the national databases in an XML format (referred to as the NTDS XSD). Your data is validated using a validator software program that is presently included in an NTDS Software Development Kit (SDK). The specific NTDS XSD and validator software previously included in that SDK was developed by the vendors (DI with collaboration from CDM, Lancet, and others) for use in end point trauma registry software and all trauma registry software systems. An SDK is what vendors use to implement these types of tools into their registry software. That specific software is now changing names and transitioning to a free-to-use SDK of the Trauma Vendor Alliance (TVA). Given this terminology, there are many things we know, and many things we don't know at this time regarding the ACS transition of its internal business systems for the operation of its proprietary ACS NTDB and ACS TQIP® databases.

Export Software - Your existing Registry Software already has existing capabilities for performing year-specific exports to ACS NTDB & ACS TQIP® by preparing data files in the format required. Prior to July 1, 2017, DI, in collaboration with CDM, Lancet, and others, designed these formats for ACS, which ACS supported and promoted. Use of these vendor-designed formats greatly simplified our efforts and costs for providing your Export Software and is the premise upon which we independently provide our software services to you. As of July 1, 2017, CDM, DI, and Lancet are transitioning our maintenance of these formats (called XSD's) to the TVA to maintain them for FREE industry use. We have renamed the XSDs to make it clear the source is the TVA. BOTH the ITDX XSD (from the TVA) and any new NTDS XSD (from the ACS) are important to you! They will work together using a "converter". The new name for the vendor-designed XSD is the "ITDX." The ITDX XSD is the vendor continuation of the NTDS XSD that we provided to ACS up until July 1, 2017. The ITDX continues to be vendor-designed and developed, saving you time and money because it buffers us and you from many needless technical changes and impacts to your systems, processes, and Export Software. The ITDX is already produced "under the hood" in your existing Export Software, so your continued use of ITDX will minimize the impact to you, especially for 2018 and beyond.

Here's what we know and what we do not know, as of June 1, 2017:

- We do not know the technical specifications of the format (NTDS XSD) that will be required for NTDB 2018 data submission. (We of course have asked.)
- We do know that the NTDS XSD software that was programmed by the vendor community since 2009 will be renamed to the ITDX XSD and maintained for free by the Trauma Vendor Alliance.
- We do not know the efforts that would be involved in rewriting the exports to a new NTDS XSD format that we expect will be provided by ACS to the industry at some point in the future.
- We do not know what costs may be associated with these efforts since we do not know the technical specifications.
- We do know as of the current date that there is no funding to CDM, DI, or Lancet from ACS as of July 1, 2017 for funding this work or for supporting ongoing revisions to the required export programs.
- We do know, in contrast, that CDM, DI, and Lancet have committed to provide all of the programming changes necessary to support the ITDX 2018 export software revisions to all of their existing NTDB & TQIP exports under active maintenance at no charge to their customers.
- We do know that the ITDX will contain a free converter from the ITDX 2018 XSD to whatever the final NTDS 2018 XSD becomes (this assumes ACS continues to make the XSD format publicly available).

- We do know that your overall lowest cost solution for updating your Export Software to output NTDS 2018 XSD will be to use this free converter since it allows us to leverage your existing ITDX Export software.
- We do not know the efforts that may be involved to integrate or deploy this free converter to each and every one of our clients (with software running on ~2000 servers).
- We do know that those efforts would be greatly reduced if a converter was run and maintained at a single secure server that was made accessible to all of our users.
- We do know that CDM, DI, and Lancet offered to fund the secure hosting of a converter for ACS using the same servers and data center that we've been using to provide those same services for ACS since 2009 (which ends June 30, 2017), but that offer was not accepted. Had it been, there would have been little to no impact to our users, as your data submission to the prior site would simply have automatically connected your data to the new systems and features of ACS.
- We do know that CDM, DI, and Lancet will be independently providing you with options (time, cost, if any, methods) for running this converter as a seamless integrated component of your existing Export Software, once we are provided with technical specifications by ACS.
- **Bottom line.** Your existing Export Software already supports the ITDX XSD and has supported it since 2009. It will be enhanced to support the new NTDS 2018 XSD via a converter. How and where this converter will be integrated with your Export Software is TBD, as we are waiting for ACS to provide technical details to us.

Validation Software - Your software has a built-in validator module that was designed and built by DI, in collaboration with CDM, Lancet, and others, which ACS has supported and promoted since 2009. This greatly simplified our efforts and costs for providing your Validation Software and is the premise upon which we make our respective independent contractual commitments to you. As of July 1, 2017, CDM, DI, and Lancet are transitioning the maintenance of our validation software to the TVA for FREE industry use. We are renaming the existing validation software to the “Vendor Validator” to help avoid confusion going forward. In the past our validation software was used on both the “Export side” and “Receiving side” of ACS NTDB and ACS TQIP® due to vendor roles with ACS. BOTH validators are important, and they will work together by a channel connector. The Vendor Validator™ is the vendor continuation of the validation software that we provided to ACS up until July 1, 2017 under the NTDS SDK name. The Vendor Validator™ is vendor-designed and developed, saving you time and money because it buffers us and you from many needless technical changes and impacts to your systems, processes, and Validation Software. The Vendor Validator™ is already included "under the hood" in your Registry Software, so your continued use of the Vendor Validator™ will minimize the impact to you, especially for 2018 and beyond. Here's what we know and what we do not know, as of June 1, 2017:

- We do know that the validator software that has been used since 2009 can no longer be maintained by ACS after July 1.
- We do know that the validator software that you have been using for years is not owned by ACS and has been donated by the vendors to the TVA and renamed the Vendor Validator™.
- We do know that the Vendor Validator™ will be maintained for free by the Trauma Vendor Alliance as a customer service to the industry.
- We do know that the Vendor Validator™ has channels to support NTDB data formats from 2009-2017 and TQIP data formats since TQIP's inception.
- We do not know what prior years will be supported by any new validator software provided by ACS.

- We do know that we each have substantial functionality written around the current Vendor Validator™ software in our respective registry software which is important to us, our products, and we believe, to you, our respective clients.

- We do not know any technical details or timelines of a new validator software that will be provided by ACS at some point in the future.

- We do not know the efforts that would be involved in integrating, testing, or deploying a new validator software across our large national and international user base.

- We do know that the Vendor Validator™ will include a "channel" that will allow you to connect to whatever new ACS validator may be coming in the future (provided ACS provides a Validator that allows 3rd party vendors to write programs to use it).

- We do not know the efforts that will be involved in deploying and supporting the integration of that new ACS channel across our client bases (again, ~2000 servers and thousands of installations).

- We do know that CDM, DI, and Lancet will provide solutions and options for each and every one of our systems that presently uses the validator to be able to access all prior year channels and all 2018 and future year channels.

- We do not know the efforts and costs that will be associated in providing this solution until we have been provided with the technical information and details that are needed to transition a massive nationwide infrastructure for data collection, validation, and national aggregation.

- We do know that updating changes at a single server location will be less costly than making those changes at thousands of server locations.

- We do know that those efforts would be greatly reduced if a portion of that solution was run and maintained at a single secure server made accessible to all of our users.

- We do know that CDM, DI, and Lancet offered to fund the secure hosting of a real-time "connector" to ACS using the same secure servers and data center that we've been using to provide validation services for ACS since 2009 (which end June 30, 2017) but that offer was not accepted. Had it been, there would have been little to no impact to our users, as your data submission to the prior site would simply have connected to the new validation software and would automatically connected your data to the new systems and features of ACS.

- **Bottom line.** Your existing Validation Software already supports the Vendor Validator™ and has supported it since 2009. It will be enhanced to support the new NTDS 2018 Validator via a channel. How and where this channel will be integrated with your Validation Software is TBD, as we are waiting for ACS to provide technical details to us.

NTDB & TQIP Data Submission & Compliance

- We do not know any technical details of the new website that will be used to receive your data files in the NTDS 2018 XSD format.
- We do know that DI, CDM, and Lancet will be providing solutions for each and every one of our respective clients that presently submit to NTDB and ACS TQIP® by leveraging the ITDX 2018 XSD. See **Export Software** discussion above.
- **Bottom Line.** We do know that the ITDX 2018 will be sufficient for meeting all clinical and data dictionary requirements of the NTDS 2018. ITDX should be adopted as a “base submission

format" for all NTDB and NTDB-based submission processes supported directly or indirectly by any of us for Hospitals.

State Data Submission

- We do know that certain States, Regions, and Systems have adopted the NTDS XSD as the "foundation" for their custom registries.
- We do know that the NTDS 2018 XSD will be the first XSD for NTDB and ACS TQIP® that was not designed by one of the leading, established, hospital trauma registry vendors (CDM, DI, Lancet).
- We do know that CDM, DI, and Lancet have agreed to provide software support for all of our respective clients under active NTDB-based export and maintenance services to support the ITDX 2018 for free in our hospital trauma registry products.
- We do know that CDM, DI, and Lancet have agreed to provide software upgrades for our respective central site clients (States, Regions, Hospital Systems) to the ITDX 2018 for systems that presently utilize an NTDB-based submission format and adopt the free ITDX.
- We do know that no arrangements are in place for CDM, DI, and Lancet to receive any funds or support from ACS to perform similar modifications for NTDS 2018.
- We do not know what costs would be involved to make such registry modifications to your hospital or state systems based on NTDS 2018, but we do know that there are already planned differences between ITDX 2018 XSD (designed by Vendors) and NTDS 2018 XSD (not designed by us) in the areas of Complications and Comorbidities, for examples, that will require additional programming and mapping (and potentially) costs to support.
- We do know that your State, Region, or System adopting ITDX 2018 as your method for meeting national compliance with initiatives such as ACS NTDB and ACS TQIP® will help reduce or eliminate those costs.
- We do know that this will put your Hospital (or the Hospitals in your State, Region, or System) who use products such as CDM, DI, and Lancet in the best cost position with the lowest impact.
- **Bottom Line.** We do know that the ITDX 2018 will be sufficient for meeting all clinical and data dictionary requirements of the NTDS 2018. ITDX should be adopted as a "base submission format" for all NTDB and NTDB-based submission processes supported directly or indirectly by any of us for States, Regions, Systems, and the Hospitals that submit to them. This will help all stakeholders minimize cost and impact.

In short, we do know that CDM, DI, and Lancet have taken the initiative to design a number of free technologies, systems, standards, and tools (specifically including the Vendor Validator™ and ITDX) to better prepare us and you for addressing requirements as details become known. This preparation by us, and the requested adoption by Hospitals and States by you, give us the ability to provide options for you that can save time and money associated with the massive undertaking that is upon us all.

What to do next?

- If you are a Hospital using CDM, DI, or Lancet - you should continue to have us use the **Vendor Validator™**. There is no cost. You simply have to register for your free license. See the www.TraumaVendorAlliance.org web site for an explanation of the benefits and reasons for registration.
- If you are a Hospital using a different registry software, you can still register for a free **Vendor Validator™**. Your vendor will be provided with free software and ongoing support to continue your use of the Vendor Validator™ after July 1, 2017.

- If you are a State, Region, or System and adopt NTDS standards in whole or in part, you should **adopt ITDX as your "base submission format"** for your system remaining harmonized with NTDS to meet NTDB 2018 compliance requirements, while minimizing impact to your System, System Vendor, Hospitals, and applicable Hospital Registry Vendor(s). ITDX has the support of CDM, DI, and Lancet, meaning costs are reduced for your hospital stakeholders who must meet your compliance requirements. ITDX also has backwards compatibility, so you are better insulated from annual changes to NTDS that you cannot control. ITDX can always convert to NTDS, so you retain 100% compliance with national initiatives. ITDX can support EMS linkage. ITDX has innovations from the trauma vendors, such as "explicit negatives" that can save potentially millions of clicks a year for your registrars (that's a lot of FTE!) and avoid you and your reporting / epidemiologist staff from having to potentially rewrite all of your queries and reports on complications and comorbidities. The TVA will donate a custom 2018 "channel" for your State-specific NTDS-based state-specific format as well!

Stay tuned for more updates and announcements. **For now, you should just register at www.TraumaCloud.com by July 1, 2017.** Registration is harmless. Registration prepares you for an uncertain future, helps us establish a direct line of communication to all of you, and gives you an on ramp to many optional services and solutions you may be interested in now or in the future. Some of these are time sensitive. Yes, we are strongly encouraging you to register. There is no risk, cost, or IT issues with doing so. You'll typically be asked to register or use new systems all of the time when a state or national system changes. In this case, since we provide a huge component of your solution (whether you realize it fully or not), we have to also create a way for us to help you integrate with new systems rapidly, and this registration process helps with that as well.

We, your trusted vendors, have steered you well for over 30 years each. A combined 90+ years of experience is asking you to accept free software and support from us. We are donating our time, expertise, and services to help our industry meet national initiatives in the most continuous way. Don't be fooled by names. Just because something has the same name doesn't mean it is the same item or serviced by the same people or has the same support by us for you. Likewise, just because something must have a new name doesn't mean that it is new. We are the proven vendors, and we are the only vendors that can update our software. We have the responsibility to do that. So that puts us, not ACS, in charge of advising you on technical direction for our software. We felt that it was imperative to explain this transition because for years we have simply handled all of this for you behind the scenes. We can't do that any longer without you understanding what components are vital for us to continue to technically direct for our users and our industry.

We are doing this for all the right reasons -- to help you improve outcomes and save lives, to help buffer you and us from impact outside all of our control, and to help all of us save time and costs. You need only ask yourself who is charging for what and who is doing what for free to see this spirit of service and public benefit behind this flurry of communication.