ASN Compliance Tools for Your Daily Needs Webinar

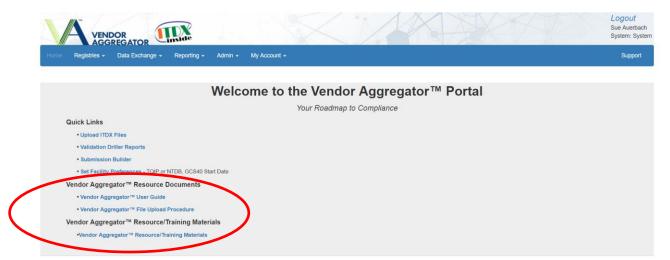
Webinar Date: 05-16-2019

Attendee Questions & Responses

- 1. Q: Are there step by step guidelines for submission to the Vendor Aggregator™, a visual step by step would be helpful as well as written instructions?
 - Q: Where do we learn how to use this new system to submit our files/data to NTDB?

A: On the home page of the Vendor Aggregator™ Portal (https://portal.vendoraggregator.com), there are quick links to a comprehensive User Guide and to Training Resource Modules. Access to the Vendor Aggregator™ Portal is only given after agreements are completed and user access is requested through the "Facility Profile" contact section in the Trauma Cloud™ portal. In addition to this documentation, ASN has and will continue to conduct webinar training sessions entitled "ASN Compliance Hub & Vendor Aggregator™ Introduction" on a regular basis which is offered to all facilities that have completed agreements and have users that have requested and received login credentials for the solution. These sessions focus on orientation to the solution with a live demonstration of how to perform key functionality including the following:

- Logging into the system
- Resetting forgotten passwords
- Setting up facility preferences
- Uploading ITDX Files
- Overview of Submission Processing Manager
- Validation Reports
- Creating file NTDS Submission Files
- Managing Exclusions



Q: We don't have our agreements signed yet, so how will we submit our data on June 1st? Q: When we called our vendors help desk to submit our data like we have in the past (bypassing ASN while the legal agreements are still being worked out), we were told that we could not do that. Has that changed? I am hopeful that the agreements will be worked out, however we would like to get our data submitted in the meantime.
Q: We are currently awaiting final approval between my hospital and ASN. If they are not done by the time data is due in a couple of weeks, how will I be able to submit my data to the State?

A: There are currently (2) participation options for using the Vendor Aggregator™ solution.

- There is a no cost option which requires the completion of a Business Associate
 Agreement and Data Use Agreement and gives ASN the ability to use data in future
 benchmarking and risk adjusted modeling activities within the ASN Network for meeting
 ACS CD15-5 requirements.
- There is also a low-cost subscription option which requires the completion of a BAA and Subscription Proposal which allows you to access and use the solution for national compliance purposes only (No Data Sharing) which includes validation and submission support on a regular basis. Pricing for the subscription option is based on your national participation level (NTDB vs. TQIP).

In addition to the ASN options, the ACS announced on April 30, 2019 that they will be accepting files in the ITDX (vendor) format so in the interim that is a short-term solution that can be considered. The ACS has also extended the 1st call for data to July 1st. We recommend that hospitals follow through with the completion of an ASN option so trauma registries can stay connected to all the current and future trauma registry tools that will allow for real-time inrecord data validation and much needed efficiencies for trauma registry operational workflow. Details about the ASN options can be further explained by your trauma registry vendor. Questions about the ACS option must be directed to the ACS for additional information; however, we note that in-record validation solutions within your vendor software cannot be met by that option alone.

3. Q: Will validation ever be done from within the registry again?

A: Yes, through a centralized connectivity method that your vendors have designed and are phasing as part of the overall ASN Compliance Hub solution. Each trauma registry software product has varying levels of validation support available to users. For products supported by Clinical Data Management, Digital Innovation and Lancet Technology, *national validation* for NTDB/TQIP starting in 2019 is now being centralized and maintained within the ASN Compliance Hub/Vendor Aggregator™. There are many advantages and reasons for this change in "how" inrecord validation will be retained. Other trauma registry vendor products can work this way as well.

 Starting in 2019, new technical requirements for the national validator have been introduced and required by the ACS. These new technical requirements are not drop-in compatible with local registry software. These technical changes would have profound

- effects on the data model currently supported in your software, the historical and legacy data in your registry and significantly impact the reporting tools (queries/reports) you currently use.
- Due to the rapid rate in which changes to the national validator are required, centralizing this functionality is much more efficient to be able to implement changes and deploy them in a timely manner. It is ideal for vendors to have 9-12 months of lead time to respond to changes and the reality is significantly less than the 4-5 months that have been allowed. So, for that reason it is far easier for us to update one location than have to update 100's of software products and work with 1,000's of IT Departments to deploy updates for every local product every time a change is required. To date, for the 2019 NTDB/TQIP validation channels we have already received seven updates from ACS that required implementation since December 2018. Because of the centralized solution all of those updates have been developed, implemented, tested and deployed within 2-3 days of receipt of the change and more importantly available to all users participating in the ASN solution.

Logistics now dictate the use of a centralized approach to allow for feasible national deployment solutions and tight timelines. But the full centralized approach does restore in-registry capability.

Q: If we choose "NOT" to share our data for benchmarking purposes, how can we participate in the Vendor Aggregator™ solution but "opt out" of future phases of the solution?
 Q: What is offered at the "no cost" vs. "low cost subscription" option?
 Q: Is there a way to get the ASN solution free without the Data Use Agreement?
 Q: If we opt out of data sharing, future Driller® opportunities and benchmarking, there is a cost for that correct?

A: There are currently (2) participation options for using the Vendor Aggregator™ solution. There is a no cost option which requires the completion of a Business Associate Agreement and Data Use Agreement and gives ASN the ability to use data in future benchmarking and risk adjusted modeling activities within the ASN Network. The no cost option is *not* permitted without a Data Use Agreement. There is also a low-cost subscription option which requires the completion of a BAA and Subscription Proposal which allows you to access and use the solution for national compliance purposes only (No Data Sharing) which includes validation and submission support on a regular basis. Pricing for the subscription option is based on your national participation level (NTDB vs. TQIP). For more information on these options, contact your trauma registry vendor.

5. Q: If we participate in the future "Driller®" benchmarking initiatives can we get ATLS Region (multiple states) benchmarking data?

A: Absolutely. One of the optional offerings of ASN will include the ability for states, health systems and PI collaboratives to implement real time benchmarking dashboards designed around your initiatives. These low cost add on services would allow interested systems to enhance existing centralized registries to have real time Driller® benchmarking reports that

benchmark within your system but allow comparison to the broader aggregate baselines. ASN is interested in and willing to work with systems whose centers are participating in the full ASN solution to implement proof of concept pilot projects. We are very excited about the ability for ASN to offer real time data aggregation that can allow states and even a collection of states to implement enhanced benchmarking opportunities. Some key advantages of the ASN approach are:

- Efficient integration with registry vendor and central site products
- The technology to perform more frequent and\ or real time data aggregator and associated PI
- The ability to utilize additional and custom clinical data points to allow implementation and measurement of topic of interest
- 6. Q: Assuming our state required uploads are handled the same way as TQIP, will there be a separate "validator" for state required fields? What about a "validator" for our facility specific fields that currently have edit checks?

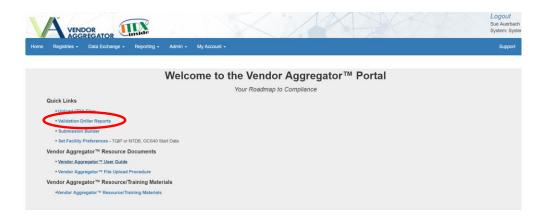
Q: How will this new process affect submissions regionally, i.e. ImageTrend?
Q: This was all about ACS Submission, which is not (now?) accepting ITDX. What about CO State?

A: The ASN Compliance Hub/Vendor Aggregator™ is currently built to support National Compliance only but has been designed for expansion to support additional submission requirements. Each region, system or state may have different data submission requirements and they should be considered separate at this time. For regional/state submissions it is recommended that you follow existing process/requirements in place for state submissions. If your state, region or system follows NTDB/TQIP exactly, the file that is produced by the ASN Compliance Hub/Vendor Aggregator™ should be able to be used for additional submission to these other systems, but it would require testing. If your state has adopted ITDX as their submission format, then your trauma registry software would be able to produce the state ITDX file locally for direct submission to the state. In terms of state, regional or system validation, those validation processes would be available through each applicable state, regional or system solutions. Many states have adopted the ITDX file format, therefore an additional solution should not be required to get your data in to the correct file format. Very few states do not offer an ITDX based solution; and all major state registry vendors (DI, CDM, Lancet, ImageTrend) have ITDX capabilities in place in various central site registry products deployments.

- 7. Q: Are any of the "Driller®" reports available to us if we do NOT provide a data sharing agreement (for benchmarking)?
 - Q: Is there cost associated with the Validation Reports or is it included at no charge?
 - Q: Can you explain again how we can access the Driller® reports?
 - Q: What reports does the Driller® tool provide that we could not get from our Drill Down Reports from TQIP?
 - Q: Do you need access to the Vendor Aggregator™ or access to the ASN Compliance Hub to utilize the Driller?

A: The Validation Driller® Analysis Reporting Module is available to <u>all</u> users of the ASN Vendor Aggregator. If you are participating via the low-cost subscription option, there are no additional costs beyond the subscription fee to access the Driller® validation reports.

The Validation Driller® Analysis Reporting Module is ASN's Data Visualization and Interactive Analysis Tool. The module utilizes data loaded into a Reporting Warehouse from the Vendor Aggregator™. The Validation Driller® Analysis Reporting Module can access patient or aggregate level (rolled-up) data based on which report is selected. As a result, users can easily analyze data and recognize trends and patterns in data quality and completeness. This tool can be used to support performance improvement efforts related to accuracy and completeness in data abstraction and can assist in identifying documentation deficiencies and or opportunities to improve the capture of quality data. Once you have access to the Vendor Aggregator™, the Driller® reports can be accessed easily from the home page by clicking on the quick link labeled "Validation Driller Reports". The user guide provides a detailed explanation on each validation report available via the Driller® tool.



A key advantage of ASN's approach to validation is its tight integration with your registry software. This means that validation that is initiated from directly within a patient record can update the tools and dashboards in Driller® real time. You can effectively work in your registry as you always have and have the tools automatically update and be available to provide you with aggregate and cross record insights into your data quality. In contrast, batch only approaches require additional manual steps and have inherent lag times. The ASN and vendor solutions work together so you can access all these centralized enhancements through your vendor software products. We are constantly innovating to expand the types of validation reports that are available to further increase your capabilities.

8. Q: Why can't the ITDX Offline Validation Tool find all the errors rather than 70-80%?
Q: Currently, there is no local validation of the NTDS elements? There is validation run on local systems currently, these are not included?

A: The ITDX Offline Validation Tool is intended to be a temporary method of validation providing users with some ability to validate data locally while in the process of evaluating ASN participation options and completing the necessary agreements required. The ITDX Offline

Validator runs checks against data in the ITDX format as opposed to the NTDS format and therefore it is impossible to include all NTDS checks in this level of validation as that would require local conversion of the ITDX file into the NTDS file format. This conversion process only occurs in the ASN Compliance Hub/Vendor Aggregator™. In addition, and due to the rapid rate in which multiple changes to the national validator are typical, centralizing this functionality is much more efficient to be able to adapt to changes and deploy in a timely manner. It is ideal for vendors to have 9-12 months of lead time to respond to changes and the reality is significantly less than the 4-5 months that have been allowed. So, for that reason it is far easier and practical to update one location than to update 100's of software products and work with 1,000's of IT Departments nationwide to deploy updates every time a change is required. To date, for the 2019 NTDB/TQIP validation channels we have already received 7 updates from ACS that required implementation since December of last year. Because of the centralized solution in place all of the aforementioned updates have been developed, implemented, tested and deployed in 2-3 days of receipt of the change and more importantly available to all users participating in the ASN solution. Maintaining the core functionality of the converter and validator in a centralized solution provides us with an economy of scale that results in quicker implementation and much improved turnaround times for all participating trauma centers.

9. Q: We are currently working on gaining access to the Trauma Cloud. Is there something we need to do to gain access to the Vendor Aggregator™?

A: Registering for the Trauma Cloud™ is the first step required in gaining access to ASN solutions. Participation in the Vendor Aggregator™ requires additional steps and the completion of agreements depending on what option you wish to participate in. There is a no cost (data sharing model) and low-cost subscriptions service (no data sharing model) that are available. For more information about gaining access to the Vendor Aggregator™ solution, please contact your trauma registry vendor.

10. Q: Is our data stored in the Vendor Aggregator™ or Trauma Cloud™ or both? This is the biggest issue our legal department is having with the agreement process.
 Q: What is the main obstacle holding back the facilities that registered with the Trauma Cloud™ in registering with the Vendor Aggregator™?

A: Patient data is only stored in the Vendor Aggregator™ solution. No patient data is stored in the Trauma Cloud™ portal. The Trauma Cloud™ is purely a master registration system for the trauma industry and provides ASN with demographic information about your facility and information about contacts at your facility. The Trauma Cloud™ is also used centrally to coordinate the registration processes for the use of various ASN Solutions. The main obstacle holding facilities back from registering for the Vendor Aggregator™ is the no cost data sharing model that ASN has available. Questions about data usage are common as well as future initiatives of ASN. ASN has legal counsel available to discuss the agreement language, data use provisions and limitations with the intent of addressing any areas of concern and questions. ASN has had the opportunity to work with hundreds of hospitals and continues to work with new facilities every day and has successfully addressed most client concerns.

11. Q: With the data you store in the Trauma Cloud™ or Vendor Aggregator™, will research projects be generated or papers written?

A: The Data Use Agreements have been designed to allow ASN to meet ACS CD15-5 requirements. Some of these requirements describe support of research. It is the intent of ASN to perform the necessary risk adjusted model development and research internally. The results of that research (not the data) will be published and made freely available to our industry to help advance the science and state of the art of performance improvement.

12. Q: Why can't the ACS do the validation through IQIVIA?

A: This is an ACS specific question that ASN cannot address, however solutions that are not provided by the vendors can only process and validate data once it has been submitted. The vendors solution, vision, and innovation entail the establishment of in record real time validation capabilities from within your existing registry software and data entry screens. This type of integration can only be provided by your registry software vendors. The primary goal of ASN is to support all ACS initiatives and most importantly keep all of our clients connected in the most cost and time efficient manner possible to national compliance. In addition, ASN prides itself on providing vendor neutral supported tools related to real-time in record validation and additional reporting opportunities to ensure registry workflow remains effective and efficient with a goal of ensuring data quality at the point of patient care.

13. Q: What is the value add of benchmarking and risk adjusted modeling when we obtain this from TQIP always (already)? As a Canadian site this does not provide any value to us.

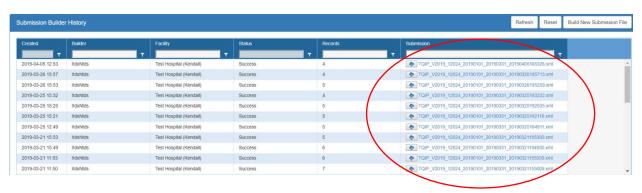
A: The benchmarking and risk adjusted modeling are additional capabilities, not intended to replace TQIP. The primary capability we are focusing on now is the real-time in record validation capability which does provide value to all registry users. We also believe there is value in having a free national trauma aggregate benchmark report that is open to all interested centers regardless of their ability to pay. This is another exciting initiative and value add function from the vendor community that we wish to restore not only to users of our software products but to the industry as a whole. The options for risk adjusted benchmarking to meet CD 15-5 requirements would be an option for sites interested in its unique capabilities (such as clinical customization beyond TQIP data elements, real-time integration, real time data aggregation and PI/Benchmarking).

14. Q: What is the expected turnaround time for the validation of a file once submitted to the Vendor Aggregator™?

A: Validation results are available immediately after the file has been successfully submitted to the Vendor Aggregator™. Each time a file is submitted and processed, a file level validation report is available for review. In addition, validator results are passed to the Validation Driller® Analysis Reporting Module where additional reports are immediately available for your review. Detailed instructions related to this functionality are of Driller® are available in the User Guide and in the Training Resource Modules available through links on the home page of the Vendor Aggregator™ portal.

15. Q: After validation how do we submit the file to TQIP?

A: The Vendor Aggregator™ features a "submission builder" function which allows you to build a final NTDB/TQIP file once you have assured that all validation results have been reviewed and data corrected/cleaned up as necessary. Once the file is built, it appears as a link in the Submission Builder Manager and is available for you to download locally to your computer or local server. Once the file is downloaded, you would manually upload it to the ACS Data Center just like you have done in the past. Detailed instructions related to this functionality are available in the User Guide and in the Training Resource Modules available through links on the home page of the Vendor Aggregator™ portal.



16. Q: The ACS has stated that they will accept ITDX files, however when uploading the files, they are being rejected. Can you please clarify the e-mail sent by ACS regarding this matter?
Q: Do we need the ASN Data Use Agreement signed in order to submit data to NTDB/TQIP?
Q: Can I submit my data to ACS if my facility does not sign the ASN BAA?

A: Like all of you, ASN was made aware by our clients that the ACS released a communication on April 30th, 2019 announcing that they would be accepting ITDX files. ASN and all the trauma registry vendors view this as a positive development and a good long-term solution. This is a tangible example of innovation and achievement by the registry vendors in gaining widespread acceptance for the ITDX file format. Although this is a positive step forward by ACS, we feel it is still vitally important for centers to consider the added value of the ASN solution as it relates to the enhancement of vendor tools for real-time in record validation which is critical to efficient registry workflow. In order to submit data directly to the ACS, the ASN Data Use Agreement and Business Associate Agreement do not need to be signed with ASN.

17. Q: Do charts have to be closed to submit to the Vendor Aggregator? Is this an automated process behind the scenes?

A: Records of any status "open or closed or both" can be submitted to the Vendor Aggregator™. It is up to your individual trauma registry program to decide how best utilize functions of the Vendor Aggregator™ into your current trauma registry operational workflow. There is no limit to how often data may be submitted to the Vendor Aggregator™. If you maintain a concurrent trauma registry, data may be validated at any point during the trauma registry abstraction process. If you maintain a more retrospective registry you may decide to validate after all data abstraction and entry is complete and records are closed. Some registry programs may opt to validate concurrently and then also do a final validation after the record is completed. It is

recommended that once data abstraction and entry is completed that you resend the completed record for final validation to ensure all validation errors are identified and corrected. The system is flexible to be able to support all validation workflows. Currently, there is no automated process behind the scenes to send records/files to the Vendor Aggregator[™]. In the near future, an automated feature will be available to support in-record real-time validation. More information will be forthcoming about this exciting system enhancement.

18. Q: Is this solution only for TQIP centers or any center? Is this work intended to compete with ACS?

A: A primary goal of ASN and all registry vendors is to support any and all ACS requirements that pertain to software and analytic capabilities. The Vendor Aggregator™ was developed to support all NTDB and TQIP centers as it relates to preparing data and files for national compliance. In addition, the solution can support centers who rely on NTDS validation for state and other system compliance purposes that may not participate in NTDB/TQIP. This solution was developed for users of our software to provide continued support for all ACS initiatives in the most efficient and manner. The Vendor Aggregator™ solution will always remain 100% harmonized with NTDS requirements while ensuring efficiencies for trauma registry work processes overall. This solution was developed with an eye to the future providing the much-needed centralized foundation and framework allowing all vendors to respond to any changes and future compliance requirements in the most cost effective and timely manner.

- 19. Q: Are validation results only available after we actually "submit" data?
 - Q: If I am registered and have signed on to the Vendor Aggregator™, am I able to validate my data?
 - Q: Can you batch validate records using the Vendor Aggregator™?
 - Q: Do we need to go back and validate individually every record?

A: National data validation results are only available after data is submitted to the Vendor Aggregator™ solution because the ACS NTDB/TQIP validation channels are only accessible in this solution. ITDX files can be generated from your local registry for an individual record or group of records (batch) and then submitted to the solution. Once you are registered for the solution and have received log-in credentials, you can begin submitting ITDX files and validating your data. It is recommended that all records meeting NTDS inclusion criteria be validated using the Vendor Aggregator™ solution to ensure that data is clean prior to submission to ACS.

20. Q: Is the Vendor Aggregator™ ready for 1st quarter 2019 NTDB Submissions?

A: The Vendor Aggregator[™] has been live since July 2018 and has all the necessary components in place required to support 2019 NTDB/TQIP compliance requirements.

21. Q: Does each person at a facility need to register or just 1 registration per facility?

A: Each facility (not every person) is required to register for the Trauma Cloud[™] and the Vendor Aggregator[™] solutions. Each facility will receive (1) set of access credentials for the Trauma Cloud[™] portal and each person that requires access to the Vendor Aggregator[™] will request and receive unique log-in credentials for the Vendor Aggregator[™] portal.

22. Q: How do we know if we are already ASN participants? If I have used the Vendor Aggregator™ to validate data, does that mean I am a participant?

A: If your facility has registered for the Trauma Cloud[™] and completed the necessary agreements to participate in the Vendor Aggregator[™] solution, then you are an active ASN participant. If you have used the Vendor Aggregator[™] solution to submit and validate data, then you are a participant in the ASN Vendor Aggregator[™] solution.

23. Q: Will I continue to initially generate my file from my local registry (ex., V5, TraumaBase, Trauma One, etc.)

A: Yes, the ITDX file will continue to be generated from your local trauma registry software and then that file will be submitted to the Vendor Aggregator™ for processing. Please note that starting with 2019 admission records, the NTDB/TQIP formatted file will not be able to be generated from your local software. This is the reason that this new centralized solution exists. The ITDX file will be submitted to the Vendor Aggregator™, converted to the new ACS technical format and then validated against the appropriate NTDS validation channels (NTDB/TQIP). When all data is scrubbed and clean, you will be able to package up a final NTDB/TQIP file within the Vendor Aggregator™ that will be available for download so you can continue to upload it to the ACS Data Center.