

**ATTACHMENT B -- TRAUMA REGIST**

**Bidder:** \_\_\_\_\_

**PROJECT EXPERIENCE**

Number of years as an Trauma Registry vendor, if applicable?

Number of state run Trauma Registry implementations, if applicable?

Number of new state run Trauma Registry implementations over the last 3 years?

What is the bidder's average state run Trauma Registry retention?

**SCOPE OF WORK SPECIFICATIONS**

**YES,  
INCLUDED**

**PROJECT MANAGEMENT**

Designated Account Manager for the life of the contract whose role is to ensure business requirements are being fulfilled and be an escalation point for questions and support.

Designated Project Manager to coordinate and schedule implementation, configuration and associated deliverables.

Bidder must provide a general project schedule of each major phase to include timeline, data migration from current vendor, implementation, configuration, testing and training.  
General project schedule must be attached to bidder response.

Upon contract award, bidder must provide a detailed project schedule that must include, at a minimum:

Business analysis

Establish test and production environments

System setup

System configuration

Data migration and configuration

Testing and acceptance

Training and assistance

**GENERAL SYSTEM REQUIREMENTS**

Bidder must provide software to comply with the National Trauma Data Bank (NTDB) and the Nebraska Trauma Registry Data Dictionary and continue to meet future NTDB and Nebraska Trauma Registry Data Dictionary (NTRDD) standards going forward at no additional cost to DHHS.

Identify a comprehensive list of hardware and software needed by users at DHHS and facilities to allow access and use of the system.

Bidder must provide a solution that is web-based and hosted by the bidder who will be responsible for the database and technical infrastructure.

Allow data collection, analysis and reporting by authorized users via a web-based application using:	
Desktops	
Laptops	
Tablets	
iPad	
Smart phones	
System(s) should be capable of functioning on common browsers.	
Operate efficiently with all Internet connections including broadband, wireless and mobile connections.	
Allow an unlimited number of users.	
The Trauma Registry system must be scalable.	
Bidder will supply a live and test environment of the proposed software solution.	
<b>TRAUMA REGISTRY FUNCTIONALITY</b>	
The system shall allow for the customization of workflows.	
Allow for users to select from lists of pre-determined answers allowed by NTDB, NTRDD or DHHS. Sort order of lists should be controlled by DHHS system administrators.	
Allow the DHHS system administrators to control validation, e.g. ability to make a data element required for the entire system.	
Questions that have validation must visually highlight the respective answer field.	
Bidder's software should provide either a score or indicate the completeness.	
The system should calculate field values whenever possible, e.g., age, Glasgow Coma Score and Revised Trauma Score.	
Allow for the development of template forms by DHHS for customized workflow and mandated questions.	
Facilities can create facility defined questions unique to the facility or use additional questions included in the software.	
Does the bidder have template forms available for DHHS system administrator modification.	
Users have the ability to save and exit a partial record without completing the record and return to finish at a later time.	
Past records can be easily retrieved for review and modification. Search parameters must be customizable.	
System should auto save patient records periodically.	
Users with multiple facility affiliations may use a single user ID and password and select the relevant facility affiliation. Users may have different security or access levels at each facility.	
Allow facilities to search and retrieve or import patient pre-hospital and referring hospital information from the DHHS Trauma Registry and/or DHHS EMS PCR systems.	
Allow for facilities to retrieve or import multiple EMS agencies PCRs for each patient.	
Allow for the upload of supplemental documentation such as pictures, pdf, word, etc.	

<b>SECURITY, SECURITY FEATURES, AND CONFIDENTIALITY</b>	
Trauma Registry must be securely accessed via internet connection.	
Trauma Registry must prevent unauthorized access to the system.	
Allow an unlimited number of end user permission groups.	
DHHS shall have full administrative rights and access over all system(s) functions.	
Meet or exceed Health Insurance Portability and Accountability Act (HIPAA). Bidder will explain how information is stored and the security to protect PHI.	
Must include procedures for safeguarding the system from unauthorized modifications.	
<p>Solution must have a Business Continuity and Disaster Recovery (BC/DR) Plan to ensure recovery of all system components in the event of a disaster. The draft version of the BC/DR Plan must:</p> <ul style="list-style-type: none"> <li>•Be submitted with the proposal;</li> <li>•Be reviewed and approved by DHHS within timeframes agreed in approved work plan.</li> <li>•Be compliant with Federal Guidelines identifying every resource that requires backup and to what extent backup is required.</li> <li>•The BC/DR Plan must, at a minimum, address the following elements: <ul style="list-style-type: none"> <li>oEstablish the purpose and scope of the BC/DR Plan;</li> <li>oAcknowledge and ensure compliance with applicable HIPAA and Health Information Technology for Economic and Clinical Health (HITECH) standards;</li> <li>oDescribe the approach and strategy to disaster recovery and business continuity;</li> <li>oEstablish roles and responsibilities for managing disaster recovery and business continuity;</li> <li>oIdentify risk areas;</li> <li>oDescribe protocols for managing disaster recovery and business continuity (during and after);</li> <li>oDescribe the approach to ongoing testing and validation of the BC/DR Plan;</li> <li>oDescribe the frequency of updates. At a minimum, the plan must be updated annually, or as needed more frequently.</li> </ul> </li> </ul>	
The solution must allow publishing data exports in industry-standard formats (XML, JSON, CSV, Excel) to support data upload into the State Data Warehouse tools and systems including platforms like Snowflake and Tableau where appropriate. The solution must export system queries into other common formats to be used externally (e.g., Excel, CSV).	
Describe how the product meets HITECH, and other security requirements.	
Provide secure system hosting, maintenance and support.	
<p>Data is to be housed on servers that are:</p> <ul style="list-style-type: none"> <li>Physically secure with procedures for control of security.</li> <li>Backed up on servers in a minimum of two (2) different locations.</li> </ul> <p>Provide detailed responses for the process, procedure and communication plan to prevent data loss, disaster recovery of data, or security breaches.</p>	

<p>Operational 99.8% of the calendar year. Quarterly reports are to be provided that identify operational status during the previous quarter and the process to notify end users the system will be down for planned or unplanned maintenance.</p> <p>Process for security audits.</p>	
<p>Bidder will describe the process they will use to report to DHHS any unauthorized access to or security incidents where data may have been compromised within 24 hours.</p>	
<p>Ability to adjust or modify facility tree structure, if applicable, to meet business needs of DHHS.</p>	
<p>The Contractor must describe their maintenance approach for their software product/solution that ensures the following:</p> <ul style="list-style-type: none"> <li>•All hardware, software, and communication components installed for use by state staff are compatible with the State’s currently supported versions of the Microsoft Operating System, Microsoft Office Suite, and the Chrome Browser, and current technologies for data interchange.</li> <li>•The Solution is browser agnostic and must be maintained, updated, and supported with a cadenced and planned schedule. DHHS currently uses Chrome as the browser standard. For provider and client-facing systems, the State of Nebraska requires that the systems support industry-standard browsers such as Chrome, Firefox, Safari, and Microsoft Edge. The Solution should support the current versions of these browsers with minimum backward compatibility for two older browser versions. The Solution roadmap should include plans to maintain compatibility with future browser versions. If a mobile application is offered, it should support both Apple and Android operation systems with at least the current OS plus the prior two versions.</li> <li>•Maintain all hardware and software products required to support the Solution at the most current to -2 version, including patches, fixes, upgrades, and releases for all software, firmware, and operating systems. Any security patches must be maintained at the most current level after thorough testing.</li> <li>•Keep current all software version upgrades within 6 months of release or with approval from State for a modified schedule.</li> <li>•Maintain a product roadmap (updated at a minimum on an annual basis) that provides details regarding planned updates, the timing of product versions/releases, end of support (EOS), and end of life (EOL) for current and past versions. The roadmap should contain information regarding third-party products that the Solution utilizes</li> </ul>	

The solution must operate and must meet the following SLA's

- The solution must be available 99.5% of the time during State business days.
- The solution must notify in advance, within one (1) business day, DHHS and other contractors when the system will be unavailable due to maintenance.
- The solution must return to operations (RTO) within 1 business day following an incident (e.g., disaster, power loss, etc.).
- The solution must provide for a two (2) hour recovery point objective (RPO) for manual updates, and as necessary to support the RTO requirement.
- The off-site system must be operational within twenty-four (24) hours following a service disruption.
- The System online access should have a response time of less than 2 seconds for queries and less than 5 seconds for inserts and updates.

Solution must have a Business Continuity and Disaster Recovery (BC/DR) Plan to ensure recovery of all system components in the event of a disaster. The draft version of the BC/DR Plan must:

- Be submitted with the proposal;
- Be reviewed and approved by DHHS within timeframes agreed in approved work plan.
- Be compliant with Federal Guidelines identifying every resource that requires backup and to what extent backup is required.
- The BC/DR Plan must, at a minimum, address the following elements:
  - oEstablish the purpose and scope of the BC/DR Plan;
  - oAcknowledge and ensure compliance with applicable HIPAA and HITECH standards;
  - oDescribe the approach and strategy to disaster recovery and business continuity;
  - oDescribe how the plan will meet the MDR specific RTO and RPOs
  - oEstablish roles and responsibilities for managing disaster recovery and business continuity;
  - oIdentify risk areas;
  - oDescribe protocols for managing disaster recovery and business continuity (during and after);
  - oDescribe the approach to ongoing testing and validation of the BC/DR Plan;
  - oDescribe the frequency of updates. At a minimum, the plan must be updated annually, or as needed more frequently.

<p>The contractor must perform an annual disaster recovery test demonstrating the efficacy of the BC/DR plan and provide an after-action report (AAR) of the test results to DHHS. The report must detail, the scope of the test, what was a success, what failed, what can be improved, and a plan to address those items. Full data restore capability must be demonstrated with no loss of data. The contractor must comply with and assist DHHS in updating and testing existing Security and Disaster Recovery/Business Resumption Plans.</p>	
<p>Solution must provide real time monitoring and alerting for all system components for performance, errors, warnings, and capacity. Also, the Contractor must submit a system performance report with actual system availability and response times to DHHS monthly. Report should calculate based on 24x7 hours less approved maintenance windows. Reports should calculate to the minute. Downtime should be calculated from a full solution level with component calculations optional.</p>	
<p>The solution integration framework must be standards-based and must meet the following</p> <ul style="list-style-type: none"> <li>•All data exchanges including inbound and outbound interfaces shall align with the MITA framework and comply with industry standards where applicable (e.g., National Information Exchange Model (NIEM), National Institute of Standards and Technology (NIST), HIPAA-compliance standards, Health level 7 (HL7), Fast Healthcare Interoperability Resources (FHIR)). (164)</li> <li>•The solution must support the use of XML/JSON standards to ensure interoperability. (159)</li> <li>•The solution must comply with the state’s existing data interface standard(s) for automated electronic intrastate interchanges and interoperability.</li> <li>•The solution must support multiple web services standards, including web services, specifications, and adapters (WSDL, WS-*, SOAP, REST, UDDI, ODATA), support standard databases such as MS SQL, SQL Server, Oracle and support integration transfer protocols such as FTPS, SFTP, HTTPS, MSMQ).</li> </ul>	
<p>Solution must monitor all integrations and interfaces. The solution must identify errors in the integrations (batch, web services, APIs) and immediately notify the required system(s) of the specific errors, where possible.</p>	

<p>The solution must provide a comprehensive framework for exchanging data with other modules and systems and should meet the following</p> <ul style="list-style-type: none"> <li>•The Solution must provide multiple mechanisms of integrating with the existing and planned Nebraska DHHS systems</li> <li>•The architecture must enable the system to exchange data efficiently, effectively, and appropriately with other participants in the DHHS enterprise</li> <li>•The solution must have the capability to implement RESTFUL API and/or SOAP-based web services for real-time integration with both State and external systems. The State prefers API first based integration approach for future planned systems.</li> <li>•When using APIs, the solution must support using the State API Gateway when interfacing within the agency and with intrastate agencies</li> <li>•The solution must support the update of data integration points with the Nebraska DHHS Systems as DHHS systems are upgraded or replaced</li> <li>•The solution must use technology-neutral interfaces that localize and minimize the impact of new technology insertion or replacement.</li> </ul>	
<p>The Contractor must design, develop, and maintain interfaces that support integration with other systems. Each Application Program Interface (API) or batch interface and components that will interface with the other modules and the Systems Integration Services will be documented using the State-provided ICD template. The Interface Control Document (ICD) which will include data layout documentation, data mapping crosswalk, inbound/outbound capability, and frequency of all interfaces. As new interfaces are required, ICDs for those will be created and shared with, and reviewed and approved by DHHS.</p>	
<p>Solution must support the use of existing data interface layouts to minimize disruption to existing systems and operations. Solution must support transferring data files using secure protocols such as SFTP. The Solution however must also support data transfer using REST APIs (Application Programming Interfaces) and implement industry standards for interfaces where existing data exchanges do not exist.</p>	
<p>The Department prefers cloud-based hosting for the solution. The delivery of the solution/services should be seamless with the hosting solution providing the flexibility to integrate other solutions for security and regulatory purposes in the future and be cost-effective and scalable.</p>	

<p>Contractor must implement, host, and manage access to the following system environments according to federal and state standards (e.g., interoperability, privacy, security, etc.):</p> <ul style="list-style-type: none"> <li>•Development</li> <li>•Test</li> <li>•Training</li> <li>•Production</li> </ul> <p>Solution must utilize these environments to allow components to be added or replaced quickly and non-disruptively.</p>	
<p>The Contractor must continuously monitor the health of the infrastructure according to the performance expectations outlined in the contract to ensure minimal impact on business operations. The Contractor must report, set alerts and reminders proactively to any degradation of the performance of the infrastructure</p>	
<p>Solution must comply with all applicable laws and regulations regarding privacy, including but not limited to the Health Insurance Portability and Accountability Act (HIPAA), DHHS IT Security Policy, NITC Standards and Guidelines, and the provisions contained in the Business Associate Agreement Provisions – Attachment C.</p>	
<p>Solution must meet and Contractor must document compliance with NIST SP 800-53 and/or NIST SP 800-171, SP 800-53A security and privacy standards, and 508 compliance/VPAT testing through the completion of a System Security Plan (SSP) per Attachment K prior to Go-Live. Contractor must provide a Plan of Action and Milestones (POA&amp;M) for any items not fully compliant.</p> <ul style="list-style-type: none"> <li>•Compliance is subject to a qualified independent security controls assessment prior to solution implementation.</li> <li>•Security and privacy control requirements may be met by confirmed attestation of compliance (e.g., FedRAMP, SOC).</li> <li>•The Contractor will be responsible for engaging a qualified independent security controls assessment contractor. DHHS shall approve the selection of the security assessment contractor.</li> <li>•Bidder must submit a sample of the SSP with the Technical Proposal.</li> </ul>	



<p>Solution must document the data sharing and security agreement for any interfaces with external information systems (e.g., solution to outside of the state's authorization boundary). The State recommends the use of CMS Interconnection Security Agreement (ISA)Template</p> <p><a href="https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/Interconnection-Security-Agreement-ISA-Template">https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Info-Security-Library-Items/Interconnection-Security-Agreement-ISA-Template</a></p>	
<p>Solution must provide an efficient and secure method for viewing and exchanging information with DHHS.</p>	
<p>Authorized user(s) must have access to user activity history and other management functions, including but is not limited to log-on approvals/ disapprovals and log search and playback.</p>	
<p>Solution must be hosted in an environment that has a Federal Risk and Authorization Management Program (FedRAMP) Certification, FedRAMP Risk Assessment that indicates compliance, has a documented NIST 800-53, or is Statement on Standards for Attestation Engagements (SSAE-16) SOC 1 Type 2 and SOC 2 Type 2 compliant.</p>	
<p><b>SYSTEM ADMINISTRATION</b></p>	
<p>Have an integrated data validation tool/module to ensure data submitted is accurate and valid.</p>	
<p>System should provide an announcement feature or similar functionality so DHHS system administrators can announce system changes.</p>	
<p><b>IMPORT AND EXPORT REQUIREMENTS</b></p>	
<p>The solution must allow publishing data exports in industry-standard formats (XML, JSON, CSV, Excel) to support data upload into the State Data Warehouse tools and systems including platforms like Snowflake and Tableau where appropriate. The solution must export system queries into other common formats to be used externally (e.g., Excel, CSV).</p>	
<p>The solution must provide a comprehensive framework for exchanging data with other modules and systems and should meet the following:</p>	
<ul style="list-style-type: none"> <li>• The Solution must provide multiple mechanisms of integrating with the existing and planned Nebraska DHHS systems</li> </ul>	
<ul style="list-style-type: none"> <li>• The architecture must enable the system to exchange data efficiently, effectively, and appropriately with other participants in the DHHS enterprise</li> </ul>	
<ul style="list-style-type: none"> <li>• The solution must have the capability to implement RESTFUL API and/or SOAP-based web services for real-time integration with both State and external systems. The State prefers API first based integration approach for future planned systems.</li> </ul>	

<ul style="list-style-type: none"> <li>When using APIs, the solution must support using the State API Gateway when interfacing within the agency and with intrastate agencies</li> </ul>	
<ul style="list-style-type: none"> <li>The solution must support the update of data integration points with the Nebraska DHHS Systems as DHHS systems are upgraded or replaced</li> </ul>	
<ul style="list-style-type: none"> <li>The solution must use technology-neutral interfaces that localize and minimize the impact of new technology insertion or replacement.</li> </ul>	
Must have interface options to allow data exchange to and from other NEMSIS and NTDB compliant systems.	
Bidder's software will provide real time validation against national and state schematron rules upon import. Validation should reject record(s) from being imported into the DHHS system upon failure to meet schematron rules. Messages must be reviewable by facilities importing data.	
Extensible Markup Language (XML) compliant with NEMSIS and NTDB.	
NTDB submission module able to export all required NTDB elements to the national trauma registry.	
Provide an importing interface for receiving data from other trauma registries and software products.	
<p>The Solution must provide a comprehensive auditing framework that provides the following features</p> <ul style="list-style-type: none"> <li>Maintain a record of all changes made to any item within the system (e.g., data element, business rule, process control, software program), the ID of the person or process that made the change, before and after images of the affected data records, and the date and time the change was made.</li> <li>Archive and retain audit data based on state retainage requirements</li> <li>Allow DHHS users to view, filter, and sort the system audit trail, and export audit data in a standardized format (e.g., XML, CSV, ASCII, and RTF).</li> <li>Provide a configurable option to allow the audit of usage by screen, by data on the screen, and by the user, based on specified timeframes.</li> <li>provide an audit trail or log which identifies all access to PHI</li> <li>Retain Audit trail or log data used to identify access to protected health information for a minimum of ten (10) years</li> </ul>	
<b>REPORTING</b>	
Provide a data analysis engine or a report generator that will provide standard (no customization) reports, ad hoc custom reporting and:	
The ability to analyze data.	
Allows approved users to generate statistical information from the aggregate patient care data through an Internet based query tool.	
Allows for dynamic and customized analysis without additional programming by the bidder.	
Creates charts with identifying labels and appropriate scientific units.	
Provides the ability to export reports into PDF®, Excel® and Word® formats.	
Provide the ability to schedule reports with various time intervals and with changing parameters.	
Specific Data Analysis requirements:	

Provide the user the ability to apply simple mathematical formulas across data element. For example, researchers need to be able to take two independent data codes and create a new data field that will contain the sum, difference, average, product, mean, median or quotient of the NTDB and NTRDD data fields.	
All data fields in the query and analysis section are to be labeled with their appropriate NTDB data code. The Trauma Registry should have hover help or some other means of identifying which NTDB data code is being collected. This will allow researchers to easily evaluate and find the proper data codes even if the data fields have been renamed for familiarity.	
Provide DHHS a live or near live data repository to be used for reporting. A data dictionary, how data is linked in tables, what the data elements are in each table, and other relevant documentation must be provided.	
Provide DHHS with the ability to import data into other DHHS systems.	
<b>TRAINING</b>	
Provide train-the-trainer instruction and materials, webinar-based training for users and on-line user manuals for instruction on use of the application with information on data elements that are current and reflect all updates.	
Provide on-site implementation training.	
Provide post go live training.	
<b>EMS PCR DATA INTERFACE</b>	
The system will interface with receiving facilities to appropriately receive EMS PCR information through data upload (preferred) or print capability.	
Interface allows for the linkage of patient outcome data from the facility and EMS agency.	
<b>SERVICE, SUPPORT AND ENHANCEMENTS REQUIREMENTS</b>	
Provide an assigned account manager for the Nebraska implementation.	
Provide a system help file available to all users.	
Provide help desk support for DHHS staff available during normal business hours. Describe what support options are available (e.g. phone, chat, support ticket, etc.).	
Support must be available 24x7x365 for critical system failures or issues.	
Provide the process or procedures for response times for all levels of support, escalation process of support, support tracking system, and support severity level determinations.	
Provide new versions released only after they have been fully tested and found to be error free and at a time mutually agreeable with DHHS.	
Provide for timely system fixes and resolution of issues deemed critical by DHHS, applied or installed after appropriate testing by the bidder and approval of DHHS.	
Have regular maintenance schedule policies, to be provided to DHHS, that explain when the system would not be available to Nebraska users.	

Improve the system based on DHHS identification of weaknesses, feature enhancements, and needed adjustments and provide a timeline for completion. Provide a description on how DHHS improvements are prioritized related to other client requests.	
Describe the process for the archival, use and retrieval for data.	
<b>DATA MIGRATION REQUIREMENTS</b>	
Migrate data from the DHHS's current provider identifying the length of time needed for conversion, testing and implementation of the proposed system(s) to full operational use by DHHS and authorized users. The steps are to include, but not be limited to:	
Defining data to be imported.	
Linking/mapping data to fit the new system.	
Testing results.	
Importing a complete set of data.	
<b>DATA OWNERSHIP REQUIREMENT</b>	
All data collected by the system(s) will be owned exclusively by the DHHS and transferrable in a format approved by DHHS to it or its designee upon contract termination/expiration.	
<b>END OF CONTRACT REQUIREMENT</b>	
The bidder shall be responsible for end of contract activities at the completion of the contract to ensure that the transition from bidder's operations by the successor or DHHS occurs smoothly and without disruption to DHHS. End of contract transition activities will include, but not be limited to, planning, transfer of data and documentation specifically for Nebraska at no additional cost in an agreed upon timeline. This obligation survives the termination of the contract.	
<b>CUSTOM PROGRAMMING</b>	
The bidder shall provide hourly pricing for any current and future custom programming needs to meet specific requirements for the Trauma Registry as requested and mutually agreed upon by the bidder and DHHS.	
<b>OPTIONAL - The following are each independent and optional only and should be included</b>	
Provide for the option to have provide patient registry data collection for:	
Cardiac Arrest and STEMI	
Stroke	
Provide integration solutions to state Health Information Exchange (HIE).	
Allow for the ability to purchase and incorporate changes provided by the Contractor.	
<b>END OF CONTRACT REQUIREMENTS</b>	

<p>The Contractor shall be responsible for end of contract activities at the completion of the contract to ensure that the transition from Contractor's operations by the successor Contractor or DHHS occurs smoothly and without disruption to DHHS. End of Contract Transition activities will include planning, timely transfer of data and documentation specifically for Nebraska at no additional cost. This obligation survives the termination of the contract.</p>	
<b>ADDITIONAL SOFTWARE FEATURES</b>	
<p>Provide a detail of any additional software features not already covered and if they are included in the cost or at additional cost.</p>	

**TRY REQUIREMENTS**

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**EXPLANATION**

**YES,  
ADDITIONAL  
COST**      **NO**      **EXPLANATION**





















