



Request for Proposal

Clinical Data Registry Services

RFP Release Date:	March 27, 2023
RFP Questions Due:	April 12, 2023, 5:00 PM CT
RFP Info Session:	May 2, 2023, 2:00 PM CT
Response to Questions:	May 3, 2023, 5:00 PM CT
Final RFP Response Due:	June 5, 2023, 12:00 PM CT
Finalists Chosen:	August 2023, expected

This RFP is considered AAP proprietary, confidential information and shall be subject to the terms of the Confidentiality Agreement entered between the parties. As such, Bidders agree to keep confidential this RFP and all information and materials which may be disclosed by AAP to Bidder's employees, agents, and subcontractors in the conduct of business under this RFP. The information in the RFP may be used only to submit a Proposal to AAP (and for no other purpose). Should a Bidder not become selected by AAP under this RFP process, it is the Bidder's responsibility to destroy all materials involved with this project.

This RFP is non-binding on the AAP, and issuing this RFP does not obligate the AAP to purchase any products or services.



American Academy
of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN®



1.0 Introduction

1.1 General

The American Academy of Pediatrics (AAP) has developed this Request for Proposal (RFP) for the purpose of selecting a supplier with a demonstrated ability to provide Managed Registry Services, including Registry Development and continuous implementation, leading Information Security and PHI data protection best practices in all phases of data storage and transport, Reporting, Hosting, Data commercialization, and Registry Support Services.

This document is intended to provide enough background information on AAP and its requirements so that prospective suppliers may make an informed Proposal with regard to this RFP. This RFP is non-binding on the AAP, and issuing this RFP does not obligate the AAP to purchase any products or services.

1.2 Overview of AAP

The American Academy of Pediatrics (AAP) is an organization of 67,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. To this end, the AAP supports the professional needs of its members. The organization's core work focuses on policy, education, and advocacy. The Child Health Improvement through Longitudinal Data (CHILD) Registry will assist the Academy in helping its members to provide the best possible care for children.

1.3 Overview of the CHILD Registry

THE PURPOSE OF THE CHILD REGISTRY IS TO ENABLE PEDIATRICIANS AND OTHERS WHO CARE FOR CHILDREN TO IMPROVE CHILD HEALTH AND WELL-BEING, THROUGH THE USE OF DATA.

We will achieve this vision by developing a clinical data registry that collects data from Electronic Health Records (EHR) systems at participating sites through automated mechanisms to build a longitudinal medical data repository for each child in the United States.

Once built, the CHILD Registry will become one of the largest repositories of pediatric data anywhere in the world and serve as the gold standard for pediatric clinical data to drive improvements in care quality and effectiveness. The CHILD Registry will leverage additional capabilities, such as natural



language processing and other emerging technologies, such as Machine Learning (ML) and Artificial Intelligence (AI), to parse unstructured clinical data, capture patient reported outcomes, reported outcomes from school staff/ clinicians and capture data automatically from connected devices and wearables.

The registry will allow translation of data into knowledge of regional and local differences in health and health care; longitudinal progression of disease; long-term safety and effectiveness of care, treatments, and devices; and risk factors for disease, enablers of well-being, and actionable data to improve care for children.

Once established, we forecast rapid growth for the number of participants in the registry. The table below includes our forecasts. Bidders are encouraged to factor this growth curve into their offerings.

	Pilot Program	Registry Launch	Year 1 Post-launch	Year 2	Year 3
Number of participating providers	200	800	4000	8500	15000
Number of participating practices	10	40	200	500	1000

For clarification – we have used the word "practice" throughout as a proxy for the institutions participating in a registry. A practice may include a solo-operating doctor clinic, an outpatient pediatric group of clinicians, a pediatric department in a hospital or health system, etc. The initial launch will include primary care settings, followed by other care settings.

1.4 CHILD Registry Objectives

The key objectives and functionalities of the CHILD Registry are to –

Short Term

- Provide data, measures and tools for continuous quality improvement and American Board of Pediatrics Maintenance of Certification activities,
- Allow for reporting of data for value-based payment,
- Provide participants with actionable information to improve care,
- Provide users with a query and analytic tool,
- Provide data for quality improvement projects

Medium Term

- Allow pediatricians to benchmark their practices and institutions to others,
- Identify variations in treatment and outcomes to ensure that children receive the best possible care,
- Provide opportunities to conduct population-based research and public health surveillance,
- Provide reliable quality and outcome measures for pediatric interventions, post-market surveillance of medication and devices, as well as clinical interventions in children,

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- Evaluate patient-reported outcomes in pediatrics

Long Term

- Inform payers, pediatricians, and federal and local governments of the best investments in child health based on quality and outcome measures for pediatric interventions,
- Identify childhood health and illness trends,
- Monitor the developmental progress of children over time,
- Predictive analytics to provide anticipated outcomes based on key factors and longitudinal data,
- Inform the development of guidelines and allow for the evaluation of the adoption of AAP clinical practice guidelines and other AAP policies,
- Allow for the integration of precision medicine information with patient data, and
- Advance the field of pediatric quality measurement through the collection of a standard set of data elements (specific types of data), and the development and testing of pediatric Digital Quality Measures
- Data reporting and analytics to support quality improvement participant activities

Our aim is to –

- Securely collect longitudinal data for patients through electronic interfaces with EHR systems
- Securely store data according to FAIR principles (findable, accessible, interoperable, reusable)
- Build a broad-based Pediatric registry that is of use to primary care pediatricians, hospitalists, industry, researchers, and specialists caring for children
- In the future, we plan to collect social and educational data, such as performance data from schools to tie health information to developmental outcomes and link data from other registries, such as immunization registries
- In the future, we plan to include patient-reported outcome data


1.5 RFP Objectives

The AAP is currently seeking solutions from suppliers to provide a clinical data registry, including hosting, onboarding of pediatric practices and institutions, automatic data acquisition from EHRs, data validation and quality management, compliance, security, reporting, data use licensing to industry, and customer support.

From the supplier's response, AAP seeks to understand vendor capabilities to meet current and future registry needs, gain a detailed understanding of specific vendor solutions, learn about vendor relationships with EHRs, and ensure that the proposed vendor solution will support the AAP's vision and business requirements.

When developing your RFP response, please keep in mind the following key requirements the AAP is seeking to fulfill:

1. Consistent, High-Quality Data – The platform must enable the highest quality of seamless data acquisition agnostic of practice EHR and automatically identify invalid or missing data across a wide variety of practice settings, from independent physician practices and multi-specialty practices to hospitals and academic medical centers. (This list of practice settings is not exhaustive.)

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2. Security – The service must be provided from a secure environment that meets or exceeds HIPAA and other healthcare industry standards regarding Private Health Information, e.g., HITRUST, SOC2 Type 2, ISO 27001 Certification.
 3. Dependable, High-Quality Service Delivery –Services must be delivered consistently with high-quality processes and data governance.
 4. Reporting – AAP seeks to improve the ability to identify and mitigate inconsistencies in the way data is captured and reported depending on the care setting and organization-specific reporting needs.
 5. Customer Support – AAP seeks to provide pediatricians and participating organizations with a quality user experience for review and extraction of their practice's or institution's data, including customer support to address incorrectly extracted or aggregated data.
 6. Analytics – To support AAP data needs, data must be accessible and able to be queried by the AAP, and ongoing technical support is required to support analytic needs. Reports and visualizations will be available within the dashboard.


2.0 Scope of services

2.1 Key Service Requirements Overview

The following sections provide an overview of AAP service requirements. Detailed requirements of service are defined in Appendix A – Functional and Technical Requirements and Bidder Response Template.

AAP expects Bidders' proposals to describe in detail the solution the Bidder is proposing, the methodologies the Bidder uses, and how the solution will fit the needs of AAP. The following aspects of the service should be included in the proposal document:

1. Hosting: this portion of the proposal will describe the hosting facilities, infrastructure, technology stack, software, service attributes, quality, scalability, resilience, disaster recovery, and security aspects (e.g., vulnerability testing, SOC) of the proposed solution.
2. Process of onboarding new practices: AAP will be adding new practices on an ongoing basis. The Bidder should provide their process for onboarding these new practices into the registry throughout the contract period and for ensuring scalability to meet increasing demand. This must include details on the technological aspects of this process.
3. Data Quality: Data quality is a top priority of this registry. The Bidder should describe their ability to maintain high quality data, identify and clean incorrect data, map data to a common registry data model, eliminate incorrectly formatted data, notify users that data is incorrect, etc. This section will describe the data model proposed, the data validation processes tool, and a description of proposed data quality dashboards and reporting tools available to the participant and AAP.
4. Automated data collection: The CHILD registry will collect longitudinal healthcare data on children all over the country from a variety of care settings, claims, and EHR systems. The AAP's constituency represents many heterogeneous practice environments, from small independent practices to large healthcare networks. The Bidder should describe in detail and demonstrate their capability in extracting data automatically from these diverse settings and different claims and EHR systems with minimal burden for participants, specifically pulling structured and unstructured data with and without patient identifiers removed.

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5. Reporting and analytics capabilities: the Bidder must identify their data reporting capabilities, including data visualization tools, dashboards, predefined other static reports, the ability to create customized reports, applying ML, AI, natural language processing (NLP) for advanced reporting and analytic tools, and manage user access to export data.
 6. Administrative restrictions: The participating practices are the exclusive owners of their own data. Participants should only have access to identifiable data within their own practices. The Bidder should describe their ability to restrict administrative access to parts of the data and provide appropriate levels of security and access while ensuring access to de-identified, aggregate data at the local, regional, and national levels for benchmarking purposes.
 7. Longitudinal Patient Data: The CHILDR registry is intended to collect longitudinal data. Patients will receive treatment at multiple clinical sites. The vendor must describe how they can track and aggregate patient data for a single patient (e.g., probabilistic matching) and assign a unique patient ID.
 8. Data licensing: The AAP is interested in licensing the use of de-identified data to industry partners such as pharmaceutical companies and device manufacturers. The Bidder should include their approach to supporting data use licensing and include appropriate commercial models for data use licensing.
 9. Patient generated health data: In a later phase of the registry, we are interested in capturing patient reported outcomes (PRO) and other patient generated health data. The Bidder must include an overview of their capability in soliciting and capturing this data and any future capabilities, such as collecting data from wearable devices.
 10. Support for measure development: The CHILDR Registry is not a Quality Clinical Data Registry (QCDR) and is not intended to support Merit-Based Incentive Payment Systems (MIPS) reporting. The Bidder should include an overview of their capabilities in meeting any prospective regulatory and private payer reporting requirements, e.g., CHIPRA. The Bidder must be able to support AAP in developing registry metrics and indicators and testing and implementing licensed and non-licensed quality measures.
 11. Software development methodology: The CHILDR Registry's development and implementation will be iterative based on continuous feedback and the changing healthcare landscape. The Bidder must include a detailed description of their approach and methodology to accommodate this approach, such as agile, scrum, waterfall, etc., including cost-effectiveness and efficiencies in the methodology.
 12. Intellectual Property assumptions: AAP is the owner of all rights to the Registry, including but not limited to the aggregate data; all data fields, data elements, datasets, databases, and data dictionaries developed by and for the Registry; any and all knowledge and reports based on the Registry data, and all information derived (including, without limitation, all risk algorithms and associated Beta coefficients and Y intercepts); and all trademarks, trade secrets and all other intellectual property arising from or reflected in the Registry, with the exception of Participant's data.
 13. Exclusions: AAP is expecting a complete registry service according to Appendix A. Anything that is not included in the proposed solution that AAP is expected to provide should be specifically called out.
 14. Termination: This section discusses how in the event of a termination of the relationship, data will be transferred to the control of the AAP or a third party, and assurances will be given that data will be completely removed from the hosting service.

Specific Business and Technical Requirements for this RFP may be found in Appendix A.

3.0 Structure of Business Response

3.1 Introduction

AAP is aware that responding to a Request for Proposal (RFP) can be a complex, time-consuming task. The process of evaluating each of the responses received by AAP is equally complicated and requires substantial resources.

Throughout this RFP, bidders are asked to comply with certain aspects, such as the provision of certain information and how information should be shown. The sole purpose of such compliance is to assist AAP in evaluating each response. Therefore, any change, unless previously approved by AAP's project team before submitting a proposal, may exclude the Bidder from further consideration.

3.2 Proposal Contents

The Bidder is to respond to each section of the RFP as outlined below. Missing sections will cause the proposal to be considered incomplete and may be removed from further consideration.

Sec. No.	Name	Contents
1	Cover Page	The Bidder is to provide a cover page containing the Bidder's name, the name of this proposal, the Bidder's contact name, and the Bidder's contact details.
2	Table of Contents	Self-explanatory
3	Executive Summary	An executive overview that contains key bidder information, an overview of the Bidder's planned solution, and a summary of the Bidder's pricing proposal
4	Introduction	Self-explanatory
5	Services Description and Scope	<p>The Bidder must provide a detailed description of their proposed solution.</p> <p>The Bidder should also include a narrative on how they will deliver the services.</p> <p>The Bidder should include in this section those requirements listed in Section 2. Scope of Services above.</p>
6	Service and Account Management Organization	The Bidder will provide a detailed description of the proposed management and governance procedures to be in place when the service commences, including but not limited to project management and executive sponsorship from the vendor. AAP intends to monitor



	(people, structure, reporting, etc.)	the quality of services provided to members and requests the Bidder to propose a method for accomplishing this.
7	Service Level Agreement	The Bidder will propose service levels that are designed to ensure delivery of services is aligned with AAP's expectations and that all standards are met.
8	Pricing	<p>The Bidder must provide a pricing proposal that clearly identifies one-time charges and recurring charges, assumptions, and volumes.</p> <p>The Bidder may also include a narrative on pricing.</p> <p>The pricing section must be comprehensive and include all costs AAP can expect to incur with the Bidder's solution, including training, data storage, hosting, ongoing support, custom development, etc.</p>
9	Data licensing	The Bidder must provide an overview of any services they provide for data licensing, either by themselves or in working with a partner, along with a proposed commercial model and a forecast for the revenues they can generate.
10	Qualifications	The Bidder will provide a description and examples of what makes them uniquely qualified to provide these services.
11	References, Insurance, Experience & Financial Statements	<p>The Bidder is to include three (3) references in its proposal, including the customer's full contact details and full details of their experience.</p> <p>Please provide three (3) years of financial statements in their entirety.</p> <p>Please confirm the level of coverage that Bidder's insurance will provide against claims arising from the disclosure of private information held in the registry, including but not limited to intentional, fraudulent or criminal acts of the Bidder, its agents, or employees.</p>
Appendix A – AAP Functional and Technical Requirements and Bidder Response Template		<p>The Bidder must complete Appendix A, included with this RFP, and return it with their proposal.</p> <p>The Bidder must clearly explain how each of the services will be provided rather than simply stating that the services can or cannot be provided in the space provided in Appendix A</p>

3.3 Additional Proposal Preparation Instructions

- The inclusion of unnecessary and unsolicited marketing materials should be avoided.
- Bidders should clearly identify if any of the services are planned and not yet developed or actively being used by the Bidder in an active/production registry. Features not yet developed should clearly be identified as on the Bidder's product 'roadmap'; the extent of the pilot testing process and the expected go-live date of that feature should be identified.

- Bidders should clearly identify if any services are planned to be delivered via a third-party subcontractor and confirm that all costs associated with third parties are included within their pricing proposal.
- Bidders should either declare that they have no existing or pending conflicts of interest in regards to the CHILD Registry or include those conflicts.

3.4 Responding to RFP Requirement / Questions in Appendix A

To enable the AAP bid management team to evaluate bidder responses, responses to all questions and requirements should be in the form of a "YES" or "NO" answer and detail how the Bidder meets the requirement.

Bidders shall describe any deviations, necessary product enhancements, and system modifications when their solution does not match the stated requirement with one hundred percent (100%) accuracy. No matter how insignificant a deviation or immaterial an AAP-specified feature or element may seem, bidders shall clearly identify every feature, data element, or other aspects of your product or services that will not be provided exactly as specified by AAP.

Bidders shall separately identify features or aspects of their product and related services that exceed AAP's specifications and explain the specific manner by which AAP will benefit from the additional functionality. A discussion of how these additional features could benefit the goal of the AAP in generating the registry would be helpful. Bidders shall clearly delineate whether the functionality is incorporated as part of your product and whether standard service is available as an option.

Any charge to AAP for an additional fee for a specification augmentation shall list the cost separately from the basic product offered in the pricing section.

Proposals shall be fully detailed, clear, and provided in a narrative fashion. Indefinite responses, such as "noted" or a link to a website, are unacceptable and will be deemed non-responsive. (Links to a website may be included only in support of a response.) **Where there is no response to a question or instruction, the proposal will be deemed non-compliant with the requirement. Where a bidder is unwilling to accept a condition, the non-acceptance must be clearly stated. Incomplete submissions may be disqualified or assessed solely on the data received with the proposal.**

4.0 RFP Timeline and Response Process

4.1 Contact Information

Please do not contact anyone at AAP about this RFP except the following single point of contact:

Contact Name	Email Address
Bianca Agregado	bagregado@aap.org

4.2 Proposal Submission and Schedule Dates

Bidder proposal submissions shall be prepared straightforwardly and concisely, identifying clearly and succinctly any deviations, service enhancements, and other differences between the RFP, the cost



elements, and the proposed services to be provided. Emphasis shall be placed on responsiveness to the RFP requirements, completeness, and clarity of content, and conformance to the RFP instructions.

Proposals shall include a Table of Contents with page numbers and section tabs, references to all exhibits and other included materials, and sufficient detail to facilitate easy reference to all requested information. In addition, the Bidder shall include responses in a thorough but concise manner using the predefined template in Appendix A.

Submission of complete and accurate information as well as competitive pricing in your response is essential to the expeditious completion of the evaluation and selection process. Therefore please read these requirements and instructions carefully and then respond in the prescribed format with all the information requested. Failure to provide the information in the prescribed format or not replying in the time period stated may lead to your company being de-selected from the process.

Bidder proposals in response to this RFP are due on June 5, 2023, at 12:00 PM Central Time


Final RFP Response Due:	June 5, 2023, 12:00 PM CT
Bidder Finalists Chosen:	August 2023, expected

Date	Event
3/27/2023	Distribute Request for Proposal to bidders via email.
4/12/2023	Bidder questions due to AAP via email to bagregado@aap.org. Due no later than 5:00 PM Central Time
5/2/2023	RFP Information Session
5/3/2023	FAQ document available
6/5/2023	Bidder responses due to AAP via email to bagregado@aap.org. Due no later than 12:00 PM Central Time
August 2023	AAP may choose to select a few bidders with which to complete due diligence and negotiate in a reasonable timeframe

AAP does not guarantee the above schedule and reserves the right to modify this schedule to best meet its needs. AAP is not liable for any costs incurred by the bidders in the preparation of their response.

Bidders are to provide responses electronically via email by the RFP due date and time.

We are looking for bidders to propose innovative, tailored, and value-adding solutions to AAP. The inclusion of marketing literature and sales materials as a response is strongly discouraged.



Proposals received other than through the designated AAP channel or after the RFP due date and time will be rejected. The Bidder is responsible for ensuring that its proposal is submitted via email on or before the RFP due date and time.

4.3 RFP Evaluation

AAP intends to establish a committee of reviewers to evaluate each Bidder based on its written proposal. The contract will be awarded to the Bidder (s) submitting the most economically advantageous proposal that best meets the criteria listed below (in no particular order).

- a. Strategic and corporate fit, including the Bidder's vision and approach with respect to best practices for developing, running, and maintaining a quality data registry
- b. Solution that best meets the needs of AAP
- c. Cost vs. benefits and flexibility, including Bidder's pricing model, total and incremental cost, and ability to generate revenues to offset our cost.
- d. Flexibility of offering (services, scope, pricing)
- e. Bidder experience and track record
- f. Evidence of the ability to work as a team with AAP and operate in a proactive manner
- g. Cultural fit with AAP
- h. Quality of service guarantees
- i. Fair and balanced contractual terms and conditions

4.4 Bidder Selection and Contracting Process

AAP will run a structured bidder selection and contracting process. The process will involve the following:

- The distribution of this RFP and the follow-on period of bidder questions and responses
- A structured evaluation of proposals provided in response to the RFP, including evaluation of presentations given by bidders
- Final selection of bidders to be included in the competitive negotiation process
- Completing a competitive negotiation resulting in a finalized contract

4.5 Questions about this RFP

Any information previously provided to a bidder regarding the sourcing of the CHILD Registry is superseded by the information in this RFP. AAP intends to manage the RFP process in a manner that provides all bidders with access to the same information. Therefore, all questions regarding the RFP should be submitted **in a single consolidated email** to Bianca Agregado. Answers to bidder questions will be distributed to all RFP recipients to ensure equity within this process, so please refrain from personalizing your questions.

AAP reserves the right to refrain from answering any questions relating to this RFP. **The latest date for receiving questions from bidders is April 12, 2023, at 5:00 PM Central Time.**



4.6 Proposal and Proposal Format

Section 3 of this RFP provides detailed instructions for developing and submitting proposals. Also included is a standardized Requirements (Appendix A) form that all bidders are required to complete and submit along with the RFP. **All RFP submissions must be compliant with these instructions. Failure to comply may result in the proposal not being accepted.**

5.0 General Conditions

5.1 Basis of Offers

Information provided pursuant to this solicitation will be used by AAP for its own use. Accordingly, all proposal responses shall become the property of AAP.

5.2 Submission of Proposals

Bidding on the Scope of Work - Bidders shall bid on the entire solution outlined in Section 2 of this document.

Schedule and Submittal Dates - Listed in Section 4.2 are the important actions, including the dates and times by which they are to be taken or completed. AAP does not guarantee the schedule and reserves the right to modify this schedule. All bidders will be notified in case of modifications to the schedule.

Proposal Submission Requirements - Bidders are required to submit an electronic copy of their proposal by email addressed to Bianca Agregado.

All proposal responses shall become the property of AAP subject to the limitations set forth in Section 5.16 related to proprietary data.

Proposals received after the RFP closing date and time will be rejected unless the delay is due to the negligence of AAP. It is the Bidders' sole responsibility to ensure that its Proposal is received on or before the RFP Closing Date and time. Hard copy, facsimile, and oral Proposals will not be accepted.

5.3 Proposal Submission and Authority to Bind

The Proposal submission should be prepared straightforwardly and concisely, identifying clearly and succinctly any deviations, service enhancements, and other differences that exist between the RFP, the cost elements, and the proposed services to be provided.

The RFP must be signed by an individual who is authorized to bind the Bidder contractually. An unsigned Proposal may be rejected. Indicate the name and title of those individuals having the agency to commit your firm to an agreement.



5.4 Proposal Preparation Costs

All costs associated with the proposal are the responsibility of the Bidder. AAP will not reimburse the Bidder, successful or otherwise, for proposal preparation and associated costs incurred as a result of this RFP.

5.5 Acceptance or Rejection of Proposals

AAP reserves the right to reject any and all Proposals. Any deviations from the guidelines set forth in this RFP may result in a Proposal being considered non-responsive and, therefore, could result in rejection of the Proposal or lower the overall evaluation score. AAP reserves the right to (i) solicit Proposals again and/or (ii) accept a Proposal without further bidding and/or (iii) to further negotiate with the selected Bidder and/or (iv) seek Proposals from other bidders.

AAP does not guarantee that an actual Agreement will result from this RFP and evaluation process. AAP reserves the right to award in whole or in part or not to make any award.

5.6 RFP Distribution

Distribution of Proposals to parties other than those specifically designated is not authorized. Failure to observe this guideline may result in Bidder's disqualification.

5.7 Validity Period

Proposals are to be valid for a minimum period of one hundred eighty (180) days after the proposal's due date.

5.8 AAP Representatives

The AAP Representative is Bianca Agregado. All questions regarding this RFP shall be submitted in writing by electronic mail to bagregado@aap.org. Therefore, a "Quiet Period" will be enforced throughout the duration of this Proposal period to ensure a fair process for all Bidders.

5.9 Supplemental and Additional Information

Bidders may be required to furnish additional information as is necessary, in the opinion of AAP, to assure that the Bidder's technical competence, proposed solution, business organization, and financial resources are adequate to perform the work requested successfully.



5.10 Cancellation

AAP may cancel this RFP for convenience at any time. However, no person has the authority to cancel or alter the bidding process except by a written declaration executed by the AAP Representative.

5.11 Effective Time for Proposals

The Bidders Proposal shall include a statement acknowledging a firm quotation period for all Services and related pricing to this RFP, which shall extend one hundred eighty (180) days from the proposal deadline, with no exceptions.

5.12 Selection

AAP reserves the right to enter into technical discussions with one or more respondents to clarify and explain the required Services to be provided to AAP.

AAP reserves the right not to award a Contract as a result of this RFP.

5.13 Performance

It should be understood that a Contract (or Statement of Work) resulting from this RFP shall be awarded on the basis that the Bidder who undertakes the Work guarantees that it possesses the necessary skills, financial resources, and ability to perform the Work. **During the performance of Services under the Scope of Work, Bidder shall not use personnel that are subcontractors or consultant employees unless pre-approved by AAP.** Bidder's loss of key personnel or facilities will not excuse the default.

5.14 Withdrawal or Modifications

Proposals may be withdrawn or modified only by written request to the AAP Contact person listed in Part 2 of this RFP prior to the time set for receipt of Proposals. No oral withdrawals or modifications will be accepted.

5.15 Award

AAP reserves the right to negotiate with any one or all of the responding Bidders on any aspect of this RFP prior to making an award. Proposals should be submitted on the Bidder's most favorable terms in response to this RFP.



5.16 Proprietary Data

Proposals become the property of AAP upon submission. AAP agrees to exercise reasonable efforts to protect all information received, provided it is expressly understood that AAP shall not be liable in the event that such information is disclosed outside AAP. All information received is subject to review by the AAP evaluation team and third parties that AAP has engaged in supporting the registry vendor selection. Bidders are cautioned to label all proprietary data as such. Proprietary data shall be handled in accordance with the terms of the Confidentiality Agreement executed by the parties.

5.17 Confidentiality

This RFP is considered AAP proprietary, confidential information and shall be subject to the terms of the Confidentiality Agreement entered into between the parties. As such, Bidders agree to keep confidential this RFP and all information and materials which may be disclosed by AAP to Bidder's employees, agents, and subcontractors in the conduct of business under this RFP. The information in the RFP may be used only to submit a Proposal to AAP (and for no other purpose). Should a Bidder not become selected by AAP under this RFP process, it is the Bidder's responsibility to destroy all materials involved with this project.

5.18 Non-exclusivity

THE PARTIES AGREE THAT THIS RFP, AND ANY CONTRACT THAT MAY RESULT FROM THIS RFP, DOES NOT ESTABLISH AN EXCLUSIVE CONTRACT BETWEEN AAP AND BIDDER NOR CONSTITUTE A COMMITMENT BY AAP, WHETHER EXPRESS OR IMPLIED, TO CONTRACT WITH THE BIDDER TO PERFORM OR SUPPLY ANY WORK; NOR IS THERE ANY GUARANTEE AS TO THE VOLUME OF WORK OR DURATION OF ANY CONTRACT. AT THE DISCRETION OF AAP, ANY PORTION OF THE WORK MAY BE PERFORMED BY AAP OR AWARDED TO ANOTHER SUPPLIER.

5.19 RFP Incorporation

By responding to this RFP, Bidder agrees that AAP reserves the right to incorporate the Bidder's RFP response in whole or in part in any resulting agreement between the parties.

5.20 Conflict of Interests

Bidders, by submission of their proposal, represent that no AAP employee other than those designated in this RFP has aided in the preparation or contributed supplemental information to the Bidder's response to this RFP.



5.21 Cost and Pricing Data

Bidder shall warrant that its rates submitted in response to this RFP are accurate, complete, and consistent with or better than rates charged to other companies for whom Bidder may be conducting similar work.

6.0 Business Terms and Pricing Proposal

6.1 Contract Duration

AAP wishes to consider a three-year agreement for the Clinical Data Registry with two one-year renewal options (for a total of 5 years). Additional options to renew thereafter on an annual basis may be considered. The contract will have an option for AAP to terminate the contract before the end of the term for any reason. The Bidder should provide costs assuming a three-year contract; termination fees and pricing for continuation after year three should be included in the proposal but itemized separately.

6.2 Compliance and Regulation

The Bidder must confirm that its services will meet and fulfill all legal and compliance requirements of the United States and any other country where services will be performed, such as HITRUST and/or ISO27001. AAP requires full compliance with HIPAA, PCI, and other applicable laws and regulations, and AAP reserves the right to audit the Bidder periodically for such compliance. AAP also expects that the Bidder will provide financial management in accordance with Generally Accepted Accounting Principles and exhibit controls in accordance with HIPAA, Sarbanes-Oxley legislation, PCI, and other appropriate laws and regulations.

6.3 Overview of Pricing Information Requirements

The Bidder shall quote all prices in \$ US. AAP is a non-profit corporation organized and operated for charitable purposes within the meaning of section 501(c)(3) of the Internal Revenue Code.

6.4 Other Infrastructure/Services

The supplier will be expected to:

- Provide all infrastructure and services required to meet RFP requirements
- Identify and demonstrate Disaster Recovery (DR) capabilities, including plan, DR test frequency, and results.
- Identify any infrastructure and services that are not included as part of their response (this is expected to be minimal, if any).



7.0 Index of Appendices

Appendices to this document are included as separate files as listed below:

Appendix A – AAP Functional and Technical Requirements with Bidder Response Template



CHILD Registry

AAP Functional and Technical Requirements

Appendix A

March 27, 2023



Contents

	Purpose	4
1	Functional Requirements	5
2	Technical Requirements	9
3	General Business Requirements	18
4	Transition Services	21



Purpose

The Child Health Improvement through Longitudinal Data (CHILD) Registry is a clinical data registry under development with the potential to substantially accelerate advances in infant, children, and adolescent health and improve outcomes by providing reliable clinical data to track the trajectory of their well-being and development from birth into adulthood.

The purpose of the CHILD Registry is to enable pediatricians and others who care for children to improve child health and well-being, through the use of data. The CHILD Registry supports three primary American Academy of Pediatrics (AAP) goals:

1. Facilitate data-driven improvements in child health care, outcomes, and well-being;
2. Assist pediatricians in their ability to deliver improved care; and
3. Positively influence the trajectory of children to healthy adults.

This registry can help pediatricians in all settings improve the care they deliver while simultaneously participating in a learning health system and supporting child health and advocacy. This registry is a tool that will drive measures of quality, national benchmarking, and promote health equity, ultimately improving the health and well-being of children. It will give pediatricians a complete picture of each child with data across health systems, health plans, and public health, creating a path towards success in value-based care with minimum burden on their practice.

To facilitate an objective process to select a registry vendor and to perform a comparative analysis of responses from different vendors, a requirements-gathering exercise was needed.

The requirements were gathered based on our conversations with members of the CHILD Registry incubator group as well as our insight and knowledge of clinical data registries. The rest of this document includes these requirements. The requirements are organized in a tabular format, which can be inserted as an Appendix into an RFP to allow vendors to respond in a consistent manner.



1 Functional Requirements

This section covers the functional requirements for the CHILD Registry. Functional requirements cover the functionality of the registry visible to users, including Administrative, Patient Registration & Management, Reporting & Visualization, and Dashboards.

	Requirements	Priority	Can you meet this requirement (Yes/No)	Notes/ Comments on Vendor approach and solution
1	Functional Requirements			
	Registry Functionality includes Administrative, Patient Registration & Management, Reporting & Visualization, and Dashboards.			
1.1.	Administrative			
1.1.1	The solution should enable AAP admin to restrict user access to certain clinical sites, such that clinical sites don't have access to aggregate data – AAP exclusively owns this data.	1-Critical		
1.1.2	The solution shall provide a user interface for clinical administrators to register new staff as needed and to provide role-based user security.	1-Critical		
1.1.3	The solution should allow the CHILD Registry administrator to manage end-users' access – including password resets, specific user access privileges, and access to system modules.	1-Critical		
1.1.4	The solution should allow the center-specific administrator to manage users within their center/ practice – including password resets, specific user access privileges, and access to system modules.	1-Critical		



1.1.5	The AAP registry administrator can track and generate reports on user access and activities within the system.	2-Highly Desired
1.2	Patient Registration & Management	
1.2.1	The solution will only allow data to be uploaded for patients who have consented to participate.	1-Critical
1.2.2	The system should have master patient index functionality and must be able to match multiple records for a single patient who is affiliated with multiple centers, e.g., using a Globally Unique Identifier (GUID).	1-Critical
1.3	Reporting & Visualization	
1.3.1	The solution must allow authorized users to view all records for a given patient across multiple clinical sites.	1-Critical
1.3.2	The solution must allow CHILD Registry users to visualize and report on national, regional, and local aggregate and site-specific data.	1-Critical
1.3.3	The solution must allow end users to export data into a variety of file formats in a secure way (including .csv, Word, Excel, SAS, SPSS, R, and STATA) for their own use when data size allows.	1-Critical
1.3.4	The solution must allow users to define custom views and data stores for specialized reporting processes for the data they are authorized to access.	2-Highly Desired
1.3.5	The default reports and visualization available to the CHILD Registry administrator should show both center-specific data and national, regional, and local aggregate data for benchmarking comparisons.	1-Critical
1.3.6	For aggregate data, it will only be made available with sufficient participants to	1-Critical



	prevent the unblinding of centers and patients.	
1.3.7	The default reports and visualization available to clinical site staff should show only center-specific data at an individual-level for benchmarking comparisons.	1-Critical
1.3.8	The system shall provide functionality and a user interface that allows defining ad hoc reports, storing report definitions, and generating reports based on the definitions.	2-Highly Desired
1.3.9	Users can generate predefined reports for specific time periods by request and based on a schedule for the data they are authorized to access.	1-Critical
1.3.10	Users should be able to submit reports to governing bodies (e.g., health agencies) once the registry is established and metrics are defined.	2-Highly Desired
1.3.11	The user interface should support generating and visualizing data analysis artifacts (plots, graphs, individual data points) based on the same parameters sites can report on.	1-Critical
1.3.12	Report and visualization implementation to follow agile methodology	2-Highly Desired
1.4	Dashboards	
1.4.1	The CHILDR Registry administrator must have the capability to provide benchmarking data at the aggregate level for each participant.	1-Critical
1.4.2	Providers within a given center must be able to view benchmarks for data within their center.	1-Critical
1.4.3	Users must be able to sort their data based on provider type for data within their center.	1-Critical



1.4.4	Must have configurable dashboards that allow end users to select and query data only on their center and at an individual clinician and patient level.	1-Critical
1.4.5	Clinical site users and site administrators must not be able to analyze detailed data from other centers.	1-Critical
1.4.6	The system must enable clinical site users to re-identify a patient from the data (e.g., for clinical trials).	2-Highly Desired
1.4.7	The solution should include administrator search functionality for various data types, such as "Match to X," "Contains X," "Start with X" for text data elements, "Equal to X," "Greater/ than X," etc.	2-Highly Desired



2 Technical Requirements

The section below lists the technical requirements for the CHILD Registry.

	Requirements	Priority	Can you meet this requirement (Yes/No)	Notes/ Comments on Vendor approach and solution
2.1	Hosting			
2.1.1	The vendor must provide data center space, infrastructure & labor services to host and maintain the registry.	1-Critical		
2.1.2	Hosting capacity must meet current registry sizing needs and scale as the registries grow.	1-Critical		
2.1.3	Data centers must include redundant power and network feeds and have a backup generator for continuous service. Please also provide details of the SLAs you are willing to commit to for solution availability and planned maintenance windows and incident escalation procedures/contacts.	1-Critical		
2.1.4	The solution must include a redundant environment with data replication and proper data backups to allow for failover in the event of an outage at the primary data center.	1-Critical		
2.1.5	The vendor must maintain and patch all infrastructure and software within the solution, including 3rd party software and hardware (i.e., Microsoft, Adobe, etc.).	1-Critical		
2.1.6	The solution must include sufficient network bandwidth within the data center to ensure the solution is available to a national group of participants and concurrent users.	1-Critical		



2.1.7	The solution must include all labor to operate the data center, maintain the operations of the infrastructure, administer the registries, and maintain the physical and logical security within the data center and the registries.	1-Critical
2.1.8	The Data Center(s) must be HIPAA, SOC2 Type2, ISO27001, and PCI compliant.	1-Critical
2.1.9	Please list other certifications/standards/designations met by the data center.	2-Highly Desired
2.1.10	The system shall be available 24 hours a day, seven (7) days a week, except for scheduled system maintenance.	1-Critical
2.1.11	Provide uptime SLA.	1-Critical
2.1.12	Provide a disaster recovery plan and include demonstrating this plan in the description.	1-Critical
2.2	Data Storage	
2.2.1	Data shall be stored in common, approved DBMS, such as Oracle, SQL+, MySQL, Postgres, etc.	1-Critical
2.2.2	What database platform do you use?	1-Critical
2.2.3	How frequently do you Implement regular automatic backups (daily, weekly)?	1-Critical
2.2.4	Ensure that stored data is encrypted, secure, and designed to withstand physical and natural disaster incidents.	1-Critical
2.2.5	Please describe the cloud-hosting services used.	1-Critical
2.3	Data Security & Compliance	
2.3.1	The solution must meet all applicable security requirements, including HIPAA, HITECH, SOC2 Type2, ISO27001, etc.	1-Critical
2.3.2	Please describe your processes for data security audits.	1-Critical



2.3.3	The vendor is responsible for maintaining compliance with regulations regarding CDRs and updating platform functionality, as needed, including maintaining compliance with licensed quality measures and code sets, e.g., NCQA, CPT codes.	1-Critical
2.3.4	Data must be encrypted during transmission and at rest.	1-Critical
2.3.5	PHI data must be logically segmented from non-PHI data within reporting stores.	1-Critical
2.3.6	PHI data should be physically segmented from non-PHI data within reporting stores.	1-Critical
2.3.7	Does your solution have the capability to engineer data elements (like age in weeks or months) that avoid disclosing PHI like DOB (e.g., shifting birthdays by a period of time so the patient cannot be reidentified)?	2-Highly Desired
2.3.8	The solution must be able to integrate with existing authentication and user profiles used by the AAP.	1-Critical
2.3.9	The solution should be able to integrate with AAP's single sign-on and user authentication mechanisms.	2-Highly Desired
2.3.10	The solution must distinguish between publicly available fields, restricted use fields, and private fields.	1-Critical
2.3.11	The solution should distinguish between publicly available fields, restricted use fields, and private fields based on metadata configuration.	2-Highly Desired
2.3.12	The solution must be able to restrict access to participants' identifiable data to only their practices and limit the visibility of individual-level data to other participants unless express authorization has been granted.	1-Critical



2.3.13	Changing information in the registry database should in no way affect the data within the participating organizations' EHRs.	1-Critical
2.3.14	The system must require authentication, such as multifactor authentication, and authorization for any user to access system modules and data.	1-Critical
2.3.15	The system must have the ability to track user activity and maintain activity logs.	2-Highly Desired
2.3.16	Intrusion Detection System (IDS), Intrusion Prevention System (IPS), Security Operations Center (SOC)	1-Critical
2.4	Data Collection and Governance	
2.4.1	Data ownership must be retained by the AAP.	1-Critical
2.4.2	The CHILD Registry will collect data from participants' EHR and claims systems through automated electronic interfaces. Please provide details of your ability and existing partnerships to extract data from claims and EHR systems.	1-Critical
2.4.3	The vendor must develop and maintain interfaces with clinics participating in the Registry. This includes updates to EHR data collection mechanisms when EHR's upgrade their systems.	1-Critical
2.4.4	The solution should integrate with additional data sources, e.g., public health datasets, social determinants of health indices, behavioral health data, and practice management systems. Please describe existing partnerships to collect these types of data.	1-Critical
2.4.5	Please describe tools and policies you use to detect and measure health inequities through the application of algorithmic decision making tools or advanced analytic tools (e.g., fairness, bias detection, health inequity metrics, etc.)	1-Critical



2.4.6	AAP must have access to a data lake with the capability to create custom data sets	1-Critical
2.4.7	The vendor is required to update the data dictionary in alignment with any changes to the database.	1-Critical
2.4.8	The vendor should utilize existing interfaces where possible to minimize the impact on practices.	2-Highly Desired
2.4.9	The vendor must establish interfaces with new practices with minimal impact on the practice.	1-Critical
2.4.10	Please describe your approach to data collection and interface development/reuse from participants. What support will you need from the participant and from AAP?	1-Critical
2.4.11	Please confirm that any interfaces that are custom developed for the CHILDR Registry will become the sole IP of the AAP.	1-Critical
2.4.12	Pediatrics is a very broad specialty, and we expect the registry participants to span the range from small, independent outpatient practices to large hospitals and academic medical centers. Please describe your experience in collecting data from this variety of practice settings and how your solution would address the unique challenges of data collection from large health systems.	1-Critical
2.4.13	The system shall allow a patient to stop participating and end additional data collection (without removing any previously collected data from that patient).	1-Critical
2.4.14	The system shall provide "Help" functionality for system users that provide documentation and educational support to assist users in navigating and using the system.	3-Nice to Have



2.4.15	The AAP wants to collect longitudinal data for each individual patient across care settings and providers. Please describe how you can incorporate a unique patient identifier to collect data.	1-Critical
2.4.16	The solution should be able to collect and handle structured and unstructured data. Please describe your ability to collect, analyze and report on unstructured data with and without removal of patient identifiers and your approach to ensuring data quality.	1-Critical
2.4.17	Please describe if your solution has the capability to perform text search and analysis on unstructured data such as physician notes.	1-Critical
2.4.18	The AAP wants to collect patient reported outcome (PRO) data. Please describe your approach to collecting PRO data.	1-Critical
2.4.19	Does your solution allow for the authoring of PRO questions so that participants can create a library of questions?	1-Critical
2.4.20	Does your solution have the ability to integrate with PROMIS measures to capture PRO data?	1-Critical
2.4.21	Do you provide the ability for an administrator to approve PRO questions before they go live to standardize the questions asked across practices?	1-Critical
2.4.22	The AAP is interested in exploring the automatic collection of patient data through the use of wearable devices. Please describe your current capabilities (and any future product plans with timelines) to integrate with wearable devices.	2-Highly Desired
2.4.23	The AAP is also interested in collecting patient-specific data in the area of school performance.	2-Highly Desired



	Please describe your ability to create custom data collection templates and online forms that can be sent for individual patients directly from the registry solution by participating clinicians to collect data on specific patients.	
2.4.24	Please describe your ability to quickly generate custom data entry forms to collect relevant, timely data on syndromic and epidemiological information around specific incidents in support of the AAP's mission (e.g., collecting structured information on the incidence of a COVID outbreak).	1-Critical
2.5	Data Quality	
2.5.1	The system shall operate in compliance with Title 21 CFR Part 11.	1-Critical
2.5.2	Please describe what mechanisms you use for proactively checking data integrity and performing data validation.	1-Critical
2.5.3	What assurance and standard processes do you provide on the validity and quality of registry data when compared to source data from participants?	1-Critical
2.5.4	The system should have functionality that enables center system administrators to quickly identify incorrect data (e.g., blank, incomplete, or incorrect data elements) from their institutions.	1-Critical
2.5.5	The system must have a data quality dashboard that allows AAP and site administrators to monitor and track data quality over time.	1-Critical
2.5.6	The system must have the ability to write rules or set flags to identify and mitigate errors in data and illogical data (based on CHILD Registry data/metric requirements, which will be defined at a later time).	1-Critical
2.6	Customer Support	



2.6.1	The vendor must provide online and on-call support for users of the registry, with minimal expected business hours of Monday - Friday 8 AM - 5 PM CT.	1-Critical
2.6.2	The vendor must provide standard service level agreements (SLAs) for customer support management.	1-Critical
2.6.3	Please provide details of your support model and list out key roles and staff who will support the AAP. As our registry grows, how will your support organization grow with us to keep pace?	1-Critical
2.7 Participant Onboarding Support		
2.7.1	Please describe your approach to onboarding new participants. For purposes of this RFP, onboarding is defined as all activities from the time a potential participant expresses interest in participating in the registry to the time their data is being collected on a regular basis and reports are being generated for their use in the registry	1-Critical
2.7.2	Provide details of your current data integration solutions, including typical timeframes to completion for different EHR vendors, data formats, and types of data connectivity currently in production.	1-Critical
2.7.3	Describe the overall process for onboarding.	1-Critical
2.7.4	Describe the role of your team and the level of resource support you provide.	1-Critical
2.7.5	Describe the involvement of AAP staff and the role they are expected to play.	1-Critical
2.7.6	Describe the involvement of staff and IT support on the part of the participants.	1-Critical
2.7.7	What are the typical timelines for onboarding a small independent practice? Please provide a range based on your experience.	1-Critical



2.7.8	What are the typical timelines for onboarding a large hospital system? Provide a range based on your experience.	1-Critical
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3 General Business Requirements

The section below lists the general business requirements for the CHILd Registry.

	Requirements	Priority	Can you meet this requirement (Yes/No)	Notes/ Comments on Vendor approach and solution
3.1	General Business Terms			
3.1.1	Please provide your standard MSA Template including:	1-Critical		(attached)
3.1.1.1	Registry Specific MSA template	2-Highly Desired		
3.1.1.2	Service Locations – where is your business based, where are your key personnel based, from which locations will services for this registry be provided, and where is the data stored?	1-Critical		
3.1.1.3	Describe your project management methodology and resources allocated while piloting the registry and ongoing project management support.	1-Critical		
3.1.1.4	Approved Subcontractors – are you using any subcontractors for this scope? And if so, please provide details.	1-Critical		
3.1.1.5	Please provide Proposed Terms for any agreement between the AAP and your firm for the registry.	2-Highly Desired		
3.1.1.6	Disaster Recovery and Business Continuity Plans	1-Critical		
3.1.1.7	Service Level Agreements that you typically provide to registry customers	1-Critical		



3.1.1.8	Governance structure for the registry	2-Highly Desired
3.1.1.9	Termination Rights and any associated Fees	1-Critical
3.1.1.10	Insurance coverage inclusive of Cyber Security Insurance	1-Critical
3.1.1.11	Limitations of Liability	1-Critical
3.1.1.12	Licensing Agreements	1-Critical
3.1.1.13	Software Escrow	1-Critical
3.1.1.14	Data ownership and rights	1-Critical
3.1.1.15	Your privacy policy	1-Critical
3.1.1.16	Ownership of IP should belong to the AAP, for all aspects of the registry, dashboards, reports, interfaces, and any other artifact developed for the registry by the vendor for the AAP.	1-Critical
3.1.2	Please provide a copy of your standard registry participation agreement and data use agreement.	2-Highly Desired
3.2	Security and Confidentiality	
3.2.1	The solution must be HIPAA & HITECH, SOC2 Type2, ISO27001 compliant.	1-Critical
3.2.2	The vendor must execute a Business Associate Agreement (BAA).	1-Critical
3.2.3	Please provide copies of HIPAA, Privacy and Security Policies and Procedures, and any other compliance procedures that you utilize.	1-Critical
3.2.3.1	Please describe your approach to security. How frequently are security audits and tests done,	1-Critical



	and what procedures do you have in place to secure data?	
3.2.4	Please provide a copy of your latest Risk Assessment and any external audits (e.g., SSAE 18).	1-Critical
3.2.5	The vendor should be able to comply with Federal research requirements.	2-Highly Desired
3.2.6	Provide AAP the ability to add flagged "fake patients" that can be searched on the dark web and web as a means to validate that data in the registry is not compromised. This "fake data" must be excluded from all reporting and analysis.	2-Highly Desired



4 Transition Services

This section covers the requirements for Transition Services for the CHILD Registry. Transition services are part of risk management, the AAP should understand the effort involved and the complexity of migrating the registry from any selected vendor to a new platform in the future if needed. Please provide details on your transition plan to support the AAP in migrating a registry away from your platform, should the need ever arise.

	Requirements	Priority	Can you meet this requirement (Yes/No)	Notes/ Comments on Vendor approach and solution
4	As part of its risk management, the AAP would like to understand the effort involved and the complexity of migrating the registry to a new platform in the future, if needed. Please provide details on your transition plan to support the AAP in migrating a registry away from your platform, should the need ever arise.			
4.1	Resolution of Business Agreements			
	The supplier must provide a transition solution that includes a project plan to address the following:			
4.1.1	Please define the staffing of the transition team.	1-Critical		
4.1.2	Please provide a step-by-step phased migration plan and processes, risks, checkpoints, and risk management plans for service continuity.	1-Critical		
4.1.3	Please include an estimated transition timeline, including software escrow transition, transfer of IP, clinical and administrative data,	1-Critical		



	processes, and procedures, as well as the destruction of copies of data.	
4.1.4	Please describe the key risks you foresee with a potential transition and your approach to mitigate them.	1-Critical
4.1.5	A key concern for the AAP is migrating any custom data interfaces. Please describe your approach to migrating data collection.	1-Critical

