



**CHIESI USA, Inc.**  
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## REQUEST FOR PROPOSALS FOR QUALITY IMPROVEMENT IN NEONATAL INTENSIVE CARE

[RFP Code: **NEO.RFP.002**]

### INTRODUCTION

Chiesi USA is committed to neonatology, working alongside the medical community to improve the level of care for preterm infants. Thanks to this important relationship, Chiesi USA has become a global partner for neonatal healthcare providers, bringing life-saving drugs to more than 80 countries worldwide, and working towards the sharing of best clinical practices.

### FOCUS

The overarching aim of this Request for Proposal (RFP) is to support progress toward evidence-based practices through quality improvement (QI) initiatives focused on standardizing care delivered to neonates with suspected or diagnosed neonatal respiratory distress syndrome (RDS), or at high risk of developing RDS.

Additionally, QI project proposals shall have identified a health equity disparity and intentionally integrated it within the QI project, to potentially address the needs of the disadvantaged population.

Therefore, Chiesi USA encourages organizations and healthcare providers (HCPs) in the neonatal intensive care space within the US, to submit a project proposal meeting **ALL THREE** of the following criteria:

- Targets preterm infants with or at risk of developing RDS in the delivery room and/or neonatal intensive care unit (NICU) in the first 72 Hours of Life (HoL)
- Project is Quality Improvement and **not research**
- Has the potential to positively impact health equity in the neonatal patient population

Applications that do not meet all three of these criteria cannot be considered.

### QUALITY IMPROVEMENT

We are seeking QI projects within the therapeutic area of neonatal RDS with the following attributes:

- Use of evidence-based literature to identify target of QI project
- Ability to identify benchmarks of QI project
- Capable of measuring baseline and outcome data
- Initial Plan-Do-Study-Act (PDSA) cycle identified with drivers included
- Multidisciplinary approach
- Identifiable, predicted potential for impact
- Plan for incremental and stepwise approach to QI including educational and resource requirements
- Goal to submit as an abstract, poster, publication, or final report to serve as an indication of completion.

The Centers for Medicare and Medicaid Services defines Quality improvement as “the framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations.”<sup>1</sup> It involves continuous efforts to identify areas for improvement, implement changes **based on evidence and best practices**, monitor the effects of those changes, and make further adjustments as needed.

Quality improvement projects differ from research in that research aims to generate new knowledge, test hypotheses, and explore the underlying mechanisms of disease, treatment modalities, or healthcare interventions. It seeks to contribute to the broader scientific understanding and may involve the development of new theories, concepts, or technologies. **This request for proposals is singularly focused on supporting quality improvement work and not research endeavors.** Research-focused projects cannot be considered.

## **NEONATAL HEALTH EQUITY**

Health inequity in the United States encompasses a range of issues that result in disparate health outcomes and access to healthcare among different populations. These inequalities are often associated with social, economic, and environmental factors. Neonatal health equity refers to ensuring that all newborns have equal opportunities to achieve optimal health outcomes, regardless of factors such as socioeconomic status, race, ethnicity, geographic location, or other social determinants of health.

All applicants shall provide a statement as to how the QI project has the potential to positively impact health equity in the neonatal population with known or suspected RDS, or at high risk of

developing RDS. Applications without this component cannot be considered. The statement may be organized around the following QI principles:

- What disparity (inequity) has been identified, and how was it measured?
- What change or part of the QI project could potentially improve/address this inequity?
- How will you know if your work has made an improvement on health equity?

Additional resource that may help inform the QI project plan and improve its potential to positively impact neonatal health equity.

- Reichman V, Brachio SS, Madu CR, Montoya-Williams D, Peña MM. Using rising tides to lift all boats: ***Equity-focused quality improvement as a tool to reduce neonatal health disparities***. Semin Fetal Neonatal Med. 2021;26(1):101198. doi:10.1016/j.siny.2021.101198  
Open Access Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8809476/>

## APPLICATION GUIDELINES

### Key Dates

- Chiesi USA RFP open for submission: August 15, 2024
- Proposal submission deadline: September 30, 2024
- Decisions will be communicated by: Dec 6, 2024
- If selected for award, execution of agreement by your institution by: March 31, 2025

### Eligibility Criteria

- In addition to the above requirements, to be eligible for funding, the primary applicant (or QI project lead) must be employed by an accredited healthcare system or hospital, accredited university, academic medical center, or research institution, located in the United States.
- We look forward to hearing from neonatal healthcare providers who are members of a multidisciplinary team interested in developing and leading quality improvement initiatives. For the purposes of this RFP, the term Neonatal Healthcare Providers includes:
  - Neonatologists
  - Neonatology and Perinatal Medicine Fellows
  - Advanced Practice Registered Nurses
  - Neonatal Nurse Practitioners
  - NICU Respiratory Therapists
  - NICU Pharmacists
- The estimated time for completion of projects should be a maximum of eighteen (18) months from the date of execution of the award agreement. Completion of the project is

defined as completion of all data collection, PDSA cycle(s), data analysis and submission of final report with budget reconciliation to the Chiesi USA Grants Program.

### Submission Process

- Go to <https://chiesi.versaic.com> and create an account to start an application.
- Use Reference RFP Code: **NEO.RFP.002** The RFP Code is required to apply.
- Submit completed applications by September 30<sup>th</sup>, 2024. Please note the RFP code will not work after this deadline and late or incomplete applications will not be accepted for review.
- Please follow the submission instructions found in the **Application Template** at the end of this document.
- Please Note for Submissions:
  - All applicants are required to submit a letter of support from their NICU Medical Director. Applications without this component cannot be considered.
  - Additionally, all applicants will need to identify in your application a designated signatory agent at your institution who will be responsible for reviewing and signing the Grant Agreement, if selected for award.

### Selection Criteria

Proposals will be reviewed for qualification by the Chiesi USA Grant Committee based on eligibility criteria, including the focus and scope as defined herein. Qualified project proposals will be judged by an expert review panel (comprised of internal and external individuals with scientific, quality improvement, health equity, and clinical expertise). The projects will be judged on several criteria, including:

- Well-defined initial and hypothesized QI cycles
- Potential for positive impact on neonatal health equity
- Well-defined multi-disciplinary team
- Alignment of project to existing supporting evidence and best practices

### BUDGET AND FUNDING

#### Budget

Up to two (2) applicants will each be awarded a grant of **up to \$25,000** (inclusive of direct and indirect/administrative costs).

A finalized budget, inclusive of direct and indirect/administrative costs approved by your institution is required on the RFP application. If there are no indirect or administrative costs

associated, please indicate indirect cost rate to be 0% in your submitted budget. The maximum allowable percentage of your total budget for indirect/administrative costs is 30%. Indirect Costs greater than 30% of your total budget will not be considered. This cannot be changed after submission.

### **Use of Funding**

- Grant Recipient will use the Funding solely for purposes of the Project. Examples of **expenses that may be funded** by the Chiesi USA Grants Program:
  - Educational content development
  - Honorarium for medical or scientific faculty, preferably for accredited education only.
  - Room rental related to the educational portion of the program
  - Costs for accreditation
  - Meeting-related expenses including A/V equipment rental (must be detailed in budget)
  - Reasonable meals or refreshments for participants allowable in the U.S. when in direct relation to the educational activity, this is limited to nominal cost meals or snacks
  
- Industry regulations **prohibit** the use of Chiesi USA grant funds for certain budget items, including but not limited to:
  - pay salary or wages, travel, lodging, registration fees, or personal expenses for Project participants.
  - purchase and distribute items to Faculty or Project participants that possess a discernible value on the open market (e.g., textbooks).
  - purchase capital equipment such as computers, Phones, tablets, appliances, machinery, camera equipment, sensors, etc.
  - purchase of durable medical devices or equipment used in the care of patients.
  - Training simulation mannikins
  - Gifts for faculty, organizers, or participants
  - Fund entertainment or recreational activities, like spa services, retreats, or dinners with no direct relation to the educational activity

### **Agreement Processing and Funding**

- Institutions selected for funding will be required to enter into a QI Education Grant Agreement with Chiesi USA. This agreement will be sent following the selection notice, to the point of contact identified in your application as the designated signatory agent for review and sign via DocuSign.



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- Chiesi requires a fully executed Agreement prior to project start date.
- An IRB review exemption/waiver confirmation will be required prior to disbursement of funding award.
- Failure of your institution to review the terms and conditions, sign, and return the Letter of Agreement by March 31, 2025 may cause forfeiture of grant funding by Chiesi

## FAQS

### **How much funding is available for an applicant that is awarded funding by Chiesi USA?**

- The total funding requests per project will not exceed \$25,000.
- Up to two (2) total applicants will be awarded a grant for this RFP.
- Requests for amounts exceeding \$25,000 (inclusive of indirect and administrative costs) cannot be considered.
- The total budget for the project may be greater than \$25,000 but not greater than \$50,000 (i.e., Chiesi funding may be no less than 50% of the project's total budget).

### **I did not include indirect costs (a.k.a. overhead) in my submitted budget. Can I revise my budget to include indirect costs after I am notified whether I am selected for a funding award?**

- No. All direct and indirect/administrative budget requirements should be addressed in the submitted budget. Please consult with the requisite department at your institution to determine whether your project is subject to a standard indirect rate.
- The maximum allowable percentage of indirect costs in the total budget submitted cannot exceed 30%. The total funding awarded per project will not exceed \$25,000, inclusive of direct and indirect costs.

### **What is an "Independent" Request for Proposal?**

- "Independent" means the projects funded by Chiesi USA are the full responsibility of the recipient organization. Chiesi USA has no influence over any aspect of the projects.

### **How long will the project and funding last?**

- The project duration will be a maximum of eighteen (18) months from the date of receipt of the signed Letter of Agreement through receipt of final report.

- If selected for award, funding will be disbursed as a one-time payment following the receipt of the following: a signed Letter of Agreement; and, an IRB review exemption/waiver.

**What should a quality improvement plan entail?**

Applicants should design and plan to implement a quality improvement project that incorporates the following:

1. Multidisciplinary team identified to perform root cause analysis for problem attempting to be solved
2. Create knowledge and build capabilities and capacity integrating performance and quality improvement with continuing education
3. Evidence-based education and/or quality improvement and follow generally accepted scientific principles
4. Utilization of system-based changes institution of well-defined PDSA cycle with baseline measurements for comparison

**Which therapeutic areas are you considering for this RFP?**

- Infants with or at risk of developing respiratory distress syndrome (RDS) in the delivery room and/or neonatal intensive care unit (NICU) in the first 72 Hours of Life (HoL)

**Is Chiesi USA considering bronchopulmonary dysplasia (BPD) prevention or management quality improvement projects for this RFP?**

- No. While BPD is a significant and costly outcome of RDS, it is not the focus of this RFP. Although strategies known or hypothesized to prevent or decrease risk of BPD may be part of the QI process, the proposal cannot be considered if focused on BPD management alone.

**If my project has two of the three required components, will it still be eligible for consideration?**

- No. All projects must (1) target preterm infants with or at risk of developing respiratory distress syndrome (RDS) in the delivery room and/or neonatal intensive care unit (NICU) in the first 72 Hours of Life (HoL), (2) be a Quality Improvement (QI) project and not research, and (3) have the potential to positively impact health equity in the neonatal patient population.



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**Health Equity is a broad term. How will I know if my Neonatal Health Equity component is sufficient?**

- The definition of neonatal health equity has been left broad by design. It is up to the applicant to detail how they believe their QI project can positively impact neonatal health equity in the therapeutic area of RDS.

**Our hospital is not an academic institution and does not have a grants office or designated person for grant administration. Can I still apply?**

- Yes. We encourage community hospital HCPs to apply. However, your grant application **must** include an authorized representative to serve as signatory and administrator of grant funds received. If you do not have a grants/awards office, we encourage you to speak with someone in your institution's financial or business department, such as the Chief Financial Officer, prior to beginning your application process.

**For questions about this RFP please contact: [us.grants@chiesi.com](mailto:us.grants@chiesi.com)**





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**QUALITY IMPROVEMENT PLAN & INSTRUCTIONS**

<b>Project Details</b>	
<b>Project Title</b>	<i>This is the name of the event or project seeking grant funding</i>
<b>Project goals and objectives</b>	<i>Briefly state the overall goal of the project. Describe how the goal aligns with the focus of the RFP and the goals of the applicant organization(s). List overall objectives you plan to meet with your project, including goals for learning and expected outcomes. Objectives should describe the target population and outcomes you expect to achieve as a result of conducting the project.</i>
<b>Assessment of Need</b>	<i>Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in your target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information.</i>
<b>Target population</b>	<i>Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population.</i>
<b>Project Design and Method</b>	<i>Describe the planned project and the way it addresses the established need. If your methods include educational activities, please briefly describe the topic(s) and format of those activities. Any plans for patient involvement or input should be outlined here. Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.</i>
<b>Health Equity Component</b>	<i>Describe how this project takes neonatal health equity into account</i>
<b>Evaluation and Outcomes</b>	<i>In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data. Quantify the amount of change expected from this project in terms of your target audience. Describe how the project outcomes will be broadly disseminated. Please outline how the outcomes of the project will be translated into delivery, addressing how they could be implemented to provide the maximum</i>



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<b>Anticipated project start and end date (DD/MM/YYYY – DD/MM/YYYY)</b>	<i>Please fill in anticipated project start and end time. The project should be completed within 18 months</i>
<b>Have you secured, or are you seeking, any other grant support for this RFP activity?</b>	<i>Please indicate if you have secured or if you are seeking any other grant support for this RFP activities (Y/N); if yes, please list secured or requested grant support</i>
<b>Award Processing</b>	
<b>Award processing information</b>	<i>Payee organization, contact name, title, address, fax number, email, Tax ID. This person typically handles award funding processing</i>
<b>Letter of Agreement information</b>	<i>Institution's signing person's (signatory) name, email, address, contact information. This person will be sent the Letter of Agreement via DocuSign for review and signature on behalf of the institution</i>
<b>Supporting Documents</b>	
<b>Final Itemized Budget</b>	<i>Uploaded as an attachment A finalized itemized budget including direct and indirect costs (max 30%), preferably in excel format. This will be uploaded as an attachment</i>
<b>Quality improvement Plan and Overview</b>	<i>Uploaded as an attachment</i>
<b>Letter of Support</b>	<i>Uploaded as an attachment</i>
<b>Cross-Functional Team List</b>	<i>Uploaded as an attachment</i>

1. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-#:~:text=Quality%20improvement%20is%20the%20framework,%2C%20healthcare%20systems%2C%20and%20organizations.>