Pfizer Quality Improvement RFP

Optimizing maternal immunization practice and vaccination access during pregnancy in Italy

Competitive Grant Program – using Expert Review Panel

Overview

It is our intent to support Quality Improvement (QI) initiatives that focus on improving and optimizing the quality of care of maternal immunization practice and the access to vaccination during pregnancy in Italy

Geographic Scope/Location of Project

Italy

Project Types and Area of Interest

Potential applicants are encouraged to utilize QI programs to address maternal immunization practice and vaccination access in areas including but not limited to:

- Clinical practice to improve the maternal immunization service quality and the access to the vaccination in pregnancy.
- Novel clinical pathways to optimize the vaccination access in pregnant women.

Key Milestones

- Application submission deadline extended: May 27th 2024
- Anticipated decision notification date: July 30th 2024
- Anticipated project start date: October 30th 2024

Funding Range and Project Length

Individual projects requesting up to EUR 50,000.00 will be considered.

The estimated total available budget related to this RFP is EUR 250,000.00.

Larger grant amounts may be considered depending on the project aope and methodology. Project length will be a maximum of 18 months

Pfizer

I. Eligibility

Geographic Scope/Location of Project:

- Italy

Applicant Eligibility Criteria

- Only organizations are eligible to receive grants, not individuals or medical practice groups (i.e., an independent group of physicians not affiliated with a hospital, academic institution, or professional society).
- Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.
- The Applicant must be affiliated with an Italian Institution
- The Applicant must be the Project Lead (PL) or an authorized designee of such individual (e.g., Project Lead's grant/research coordinator).
- The Applicant (Project Lead) must have a medical or postdoctoral degree (MD, PhD, or equivalent).
- The Project Lead must be an employee or contractor of the requesting organization.
- Requesting organization must be legally able to receive award funding directly from Pfizer International LLC, 66 Hudson Boulevard East, New York, NY, 10001. We strongly recommend that applicants confirm this with their organization or institution prior to submitting an application. Grants awarded to organizations that are subsequently found to be unable to accept funding directly from Pfizer International LLC, 66 Hudson Boulevard East, New York, NY, 10001 may be subject to rescission.

II. Requirements

Date RFP Issued

- April 4th 2024

Clinical Area

- Vaccines – Maternal Immunization

Specific Area of Interest for this RFP:

- It is our intent to support QI initiatives that focus on improving and/or optimizing maternal immunization practice and access in areas including but not limited to:
- Clinical practice to improve the maternal immunization service quality and the vaccination access such as:
    - Supporting and/or training of HCPs on disease awareness/value of maternal immunization
    - Optimizing and streamlining implementation of maternal immunization recommendations
    - Increasing knowledge of the value of maternal immunization in pregnant women
    - Addressing vaccine hesitancy in pregnant women
    - Multidisciplinary collaborations are encouraged when appropriate, but all partners must have a relevant role.
- Novel clinical pathways to optimize the vaccination uptake in pregnant women by improving vaccine access.

- Particular consideration will be given to projects intended to improve care and/or access to maternal immunization for underrepresented populations such as new immigrants or other underrepresented communities.
- It is expected that projects will be evidence-based (quality improvement) and the proposed research/evaluation will follow generally accepted scientific principles. During review the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority.
- There is a considerable amount of interest in receiving responses from projects that utilize system-based changes. Although educational efforts for grantees and patients may be entirely appropriate components in responses to this RFP, projects that include an overt description of system changes will be given high priority.

  It is not our intent to support clinical research projects. Projects evaluating the efficacy of therapeutic or diagnostic agents will not be considered.

Target Audience

- Medical from healthcare institutions with a mission related to healthcare improvement.

Disease Burden Overview

- Maternal vaccination is a well-established preventive strategy to passively protect newborns and young infants during their first months of life when they are particularly vulnerable to infectious diseases because of their immature immune systems and are at increased risk of severe disease due to physiological immaturity (such as having narrow airways which increase the risk of severe respiratory disease, bronchiolitis for example). Active immunization of pregnant women generates antibodies that are actively transferred to the fetus during pregnancy, more efficiently in the late phase, and persist during the first months of life, providing protection to the infant until natural immunity is established.

Recommendations and Target Metrics

- Routine vaccination of pregnant women against tetanus, pertussis, seasonal influenza, and covid using inactivated vaccines is well-established and is recommended by the World Health Organization (WHO) and the United States (US) Centers for Disease Control and Prevention (CDC). Many European countries implement maternal vaccination policies, but there is heterogeneity among programmes. Italian Ministry of Health recommends inactivated seasonal influenza vaccination, Covid vaccination,and Tdap vaccination between 27-36 week of gestational age. Since this year, the opportunity to prevent the neonatal bronchiolitis is become available on the Italian market, thanks to the RSVpreF vaccination, with the indication in the pregnant woman for the protection of the infants from the respiratory disease related to RSV infection; now is not included within the NIP (National Program Immunization) yet.

Gaps Between Actual and Target, Possible Reasons for Gaps

- Although the existent recommendations, in Italy the coverage of the vaccination in pregnancy shows a plurality of values, with tremendous differences among territories (regions and local sanitary units), but very slow overall, slightly better for Tdap in comparison to influenza. The median value for Tdap is around 36,5% and 8,4% for flu.
- The possible reasons could be referred to the vaccination hesitancy in pregnant women, and among Ob/Gyns and other HCPs as well; the lack of clear and structured pathways for the vaccination in pregnancy; the lack of a multidisciplinary collaboration of the HCPs involved in the maternal-baby health caring.

Barriers

- At a national level, there is a scarce link between the public health specialists and the Ob/Gyns; the topic of vaccination in pregnancy is relatively new for Ob/Gyns, so specific training and scientific explorations addressed to the HCPs could improve the HCPs engagement, crucial for a realistic vaccination in pregnancy promotion. The pluralities of the vaccination journeys in pregnancy related to the territories complicate the picture.

Current National Efforts to Reduce Gaps

- Some initiatives to recall the importance of the maternal vaccination practice are endorsed by the Scientific Societies, addressed to the HCPs. Initiatives addressed to the general population exist but are sporadic and the penetrance is difficult to evaluate

Expected Approximate Monetary Range of Grant Applications:

- Individual projects requesting up to EUR 50,000.00 will be considered. The estimated total available budget related to this RFP is EUR 250,000.00
- Award amounts include direct costs, institutional overhead costs (capped at 28% per Pfizer policy), and indirect costs.
- The amount of the grant Pfizer will be prepared to fund for any project will depend upon the expert review panel's evaluation of the proposal and costs involved and will be stated clearly in the grant agreement.

Key Dates:

- RFP Release Date: **April 4th, 2024**
- Grant Application due date: **May 15th, 2024**
- Please note the deadline is 23:59 Eastern Standard Time (e.g., New York, GMT -5).
- Anticipated Grant Award Notification Date: **July 30th, 2024**
- Grants will be distributed following a fully executed agreement and submission of Final Proposal, documentation of IRB/IEC approval (if applicable), exemption or waiver.

How to Submit:

Note: Please read this section carefully since applications submitted not following these instructions will not be accepted and will be cancelled.

- Please go to www.cybergrants.com/pfizer/QI and sign in. First-time users should click "Create your password". *[Note: there are individual portals for each grant application type. Please be sure to use the URL above.]*
- Click the "Start a New Quality Improvement Application" button.
- In the application:
- For the question "Competitive Grant?" select **Yes**
- Select the following Competitive Grant Program Name: **2024 VAC ITA MATERNAL IMMUNE QI**
- Select the following Primary Area of Interest: VAV RSV Maternal Immunization QI
- Requirements for submission:

  Complete all required sections of the online application and upload your project proposal (see Appendix) in the Full Proposal Submission field.

  If you encounter any technical difficulties with the website, please click the "Technical Questions" link at the bottom of the page.

IMPORTANT: Be advised applications submitted after the due date will not be reviewed.

Questions:

- If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Angelo Carter (Angelo.Carter@pfizer.com), with the subject line "**2024 VAC ITA MATERNAL IMMUNE QI**"

Grant Agreements:

- If your grant is approved, your institution will be required to enter into a written grant agreement with Pfizer. Please click here to view the core terms of the agreement.
- Under Pfizer's competitive grant program, modifications to grant agreements will not be reviewed unless a genuine conflict exists as between applicable law and the terms of the relevant grant agreement. Applicant is encouraged to share the core terms with counsel for approval prior to submitting an application.
- Except where prohibited by applicable law and, in any case, subject to review by Pfizer Legal, payment of grant funding may only be paid to the grantee organization.
- **Delete if not a Global RFP:** This RFP is supported by Pfizer Inc. and, if approved, payment will be sent from the United States.

Review and Approval Process

- A specific grant program RFP uses an expert review panel (ERP) to make final grant decisions.
- The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement.

Mechanism by which Applicants will be Notified:

- All applicants will be notified via email by the dates noted above.
- Applicants may be asked for additional clarification during the review period.

References

- Bibliography of relevant references.

About Pfizer Global Medical Grants

Pfizer Global Medical Grants (GMG) supports the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

Pfizer's GMG competitive grant program involves a publicly posted Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an expert review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific RFP.

For all quality improvement grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.

Appendix

Specific RFP Submission Requirements

Applications will be accepted via the online portal listed in the How to Submit section. Project Proposals/Protocols should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 15-page limit exclusive of references.

When uploading your Full Proposal please ensure it addresses the following sections:

Goals and Objectives

- Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).
- List the overall objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.

Assessment of Need for the Project

- Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a 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.

Target Audience

- 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

Project Design and Methods

- Describe the planned project and the way it addresses the established need.
- If your methods include educational activities, please describe succinctly the topic(s) and format of those activities.

Innovation

- Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
- 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.

Evaluation and Outcomes

- 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.

Anticipated Project Timeline

- Provide an anticipated timeline for your project including project start/end dates.

Additional Information

- If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here.

Organization Detail

- Describe the attributes of the institutions / organizations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project.

Budget Detail

- The budget amount requested must be in Euro (EUR).
- While estimating your budget please keep the following items in mind:
  - General organizational running costs such as legal fees, insurance, heating, and lighting etc. should be included in an Institutional Overhead (if required). These costs are not specific to a grant request and therefore, should not appear as line items in budgets. However, costs that are specific to the study (e.g., some countries require insurance to be taken out on a per-study basis for clinical research) would be acceptable to be included as line items.
    - The inclusion of overhead costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
  - Pfizer does not provide funding for capital purchases (infrastructure expenses such as equipment, purchases of software or software licenses, technology or bricks and mortar). Equipment hire/leasing is acceptable and may be included in project budget.
  - It should be noted that grants awarded through GMG cannot be used to purchase Pfizer therapeutic agents (prescription or non-prescription).
- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects. Please click here for details.