Pfizer Independent Grants for Learning & Change
Request for Proposals (RFP)
Appropriate Immunisations in Adult Patients with Immune-Mediated Inflammatory Conditions

I. Background

The mission of Pfizer Independent Grants for Learning & Change (IGLC) is to partner with the global healthcare community to improve patient outcomes in areas of mutual interest through support of measurable learning and change strategies. "Independent" means that the projects funded by Pfizer are the full responsibility of the recipient organization. Pfizer has no influence over any aspect of the projects and only asks for reports about the results and the impact of the projects in order to share them publicly.

The intent of this document is to encourage organizations with a focus in healthcare professional quality improvement and/or healthcare education to submit a letter of intent (LOI) in response to a Request for Proposal (RFP) that is related to quality improvement or education in a specific disease state, therapeutic area, or broader area of unmet need. The RFP model is a two-stage process. Stage 1 is the submission of the LOI. After review of the LOI, you may be invited to submit your Full Grant Proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer IGLC website (www.pfizer.com/independentgrants) in the Request for Proposals section and is sent via e-mail to all registered users in our grants system. Some RFPs may also be posted on the websites of other relevant organizations, as deemed appropriate.

II. Eligibility

Geographic Scope:	All European countries (including Israel, Turkey and Russia), Australia New Zealand
Applicant Eligibility Criteria:	The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; patient organisations and other entities with a mission related to healthcare improvement. More information on organizations eligible to apply directly for a grant can be found at http://www.pfizer.com/files/IGLC_OrganizationEligibility_effJuly2015.pdf. 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. For programs offering credit, the requesting organization must be the accredited grantee.

III. Requirements

Date RFP Issued:	15th February 2018
Clinical Area:	Immunisation in adult patients with immune-mediated inflammatory conditions (specifically rheumatoid arthritis (RA), spondyloarthritis (SpA) and inflammatory bowel disease (IBD)).
Specific Area of Interest for this RFP:	It is our intent to support education and quality improvement programmes that focus on ensuring that adult patients with immune-mediated inflammatory conditions (specifically rheumatoid arthritis, spondyloarthritis and inflammatory bowel disease) are receiving appropriate vaccinations, as determined by their age, gender, and specific clinical risk information such as age and use of concomitant therapies. Two categories of grant support are available: <u>Category I - Grant support available to enhance/ expand existing immunisation initiatives.</u> Eligible organisations may apply if they have a prior or ongoing project that addresses healthcare provider or patient needs as relates to increasing vaccination rates. Projects must have a proven track record of success with their educational methods and quality improvement approach. Documentation must be provided that the initiative has achieved success in the past and how additional funding can expand or improve the effort to specifically include patients with inflammatory conditions. <u>Category II - Grant support available to implement new immunisation initiatives</u> Eligible organisations may apply if they intend to commence new education and/or quality improvement programmes that aim to implement local or regional guidelines on the use of vaccines in patients with immune-mediated inflammatory conditions. For both categories, multi-disciplinary collaborations are encouraged when appropriate, but all partners must have a relevant role. Any educational initiatives involved in the proposal may target either healthcare providers, patients or a combination of the two.

	It is expected that projects will be evidence-based (education and/or 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. Projects including an educational element can find more information on principals of learning and behavior change for health professionals at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf. 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.* Information on how to submit requests for support of clinical research projects can be found at www.Pfizer.com/iir.
Target Audience:	Healthcare providers with a responsibility for adult patients with certain immune-mediated inflammatory conditions in Europe, Australia and New Zealand; including (but not limited to) rheumatologists, gastroenterologists, specialist nurses, pharmacists and primary care providers (as long as a clear link to relevant secondary care providers can be demonstrated).
Disease Burden Overview:	Incidence and prevalence studies of immune-mediated inflammatory conditions during the past decades have reported a considerable variation of the disease occurrence among different populations. Overall, the estimated prevalence of immune-mediated inflammatory disease in Western society is 5%–7%[1]. The association between immune-mediated inflammatory conditions and infections is well-established, with the increased risk attributed to the pathobiology of the conditions themselves, the potential impact of comorbid conditions, and also the sequelae of using immunomodulatory or immunosuppressive disease-modifying therapies[2,3,4,5,6,7].

	Due to these infectious risk factors, screening for infection and monitoring, as well and counselling are important issues related to the treatment of patients with immune mediated inflammatory conditions[8]. Furthermore, appropriate use of vaccination in these patients can provide an important means of helping to prevent infection and improve morbidity and mortality rates in patients with immune mediated inflammatory conditions[8,6,9,10,11]. The European League Against Rheumatology (EULAR)[12] and the European Crohn's and Colitis Organisation (ECCO)[13], the Australian Government Department of Health[14] and the New Zealand Ministry of Health[15] all provide guidelines and recommendations on the use of vaccinations in immune-mediated inflammatory patients.
Recommendations and Target Metrics:	**Related Guidelines and Recommendations** ECCO recommendations for inflammatory bowel disease (IBD) patients are that all should have their vaccine serology and immunocompromised status studied thoroughly. Further, IBD patients should ideally have vaccination performed at diagnosis of the disease and/or prior to starting immunosuppressive therapy. In general, all patients should be vaccinated for the following infectious diseases: tetanus, diphtheria and polio, varicella, human papillomavirus, influenza, pneumococcus, HBV, measles, mumps and rubella, although specific considerations for each vaccine are given within the guidance. Live attenuated vaccines should only be given to immunocompetent patients and according to the country-specific vaccination schedule [13]. EULAR also recommends that in patients with auto-immune inflammatory rheumatic disease, vaccination status should be considered in the initial work-up of patients. Additionally, it is recommended that vaccines be administered during stable disease and that live attenuated vaccines should be avoided wherever possible in immunocompromised patients. It is recommended that vaccinations can be administered during the use of disease-modifying antirheumatic drugs and tumour necrosis factor α blocking agents but should ideally be administered before starting B cell depleting biological therapy. In terms of administration specific vaccines, the following recommendations (amongst others) are made: - Inactivated influenza vaccination and pneumococcal vaccination should be strongly considered - Human papilloma virus vaccination should be considered - Herpes zoster virus vaccination may be considered [12] In view of the advances in the field, the EULAR has formed a new task in order to update the recommendations. The updated recommendations will be presented at the next EULAR meeting in Amsterdam and in the process of publication.

	The Australian Government Department of Health advise that it is particularly important to assess the vaccination history and need for additional vaccines, or further vaccine doses, for all persons who are immunocompromised or for persons who are anticipating future immunocompromise due to disease or treatment. Two important examples of vaccines routinely recommended for immunocompromised persons are influenza and pneumococcal vaccines. Annual influenza vaccination should be given to all immunocompromised persons ≥6 months of age. Immunocompromised persons may also require additional doses of pneumococcal vaccines; the timing, number of doses and type of vaccine(s) vary depending on age and the underlying risk for invasive pneumococcal disease[14]. The New Zealand Ministry of Health advise that live vaccines are contraindicated for individuals with primary immunodeficiencies. Hib, PCV13, 23PPV and Td vaccines may be used in testing for primaryimmune deficiencies, on the recommendation of an internal medicine physician. Influenza vaccine is funded and recommended for all immune-deficient individuals regardless of age[15].
Gaps Between Actual and Target, Possible Reasons for Gaps:	Whilst there is a paucity of comprehensive data detailing global vaccination rates in adults, there are a number of small, locally focused studies that indicate that a high proportion of adults (even those in high-risk populations) remain unvaccinated[16,17,18] in spite of the existence of these numerous guidelines and a significant amount of clinical evidence attesting to the importance of vaccination in patients with immune-mediated inflammatory conditions.
Barriers:	A number of potential barriers have been identified that may limit achievement of higher vaccination rates, including lack of departmental vaccination protocols or guidelines, lack of screening/vaccines history at diagnoses, lack of provision of advice to patients about the importance of vaccination, belief that the responsibility for vaccination lies solely in primary care[19] and lack of an effective reminder system[20]. Lack of understanding of vaccine schedules/vaccination indications among patients, especially those taking immunomodulatory therapies, system communication and coordination issues (determination of which providers are responsible for ensuring appropriate vaccines are recommended/administered), patient understanding and acceptance of the role for vaccines in reducing infection risk may also be creating a barrier to vaccination[21].

	In certain countries, patients are also required to pay for some/all of their non-routine vaccines creating an obvious economic barrier to vaccination that will be unavoidable for some[22,23]. Whilst there are clearly some economic and logistical factors behind lower than optimal vaccination rates, vaccine hesitancy may also play a role. Vaccine hesitancy is defined as "a behaviour, influenced by a number of factors including issues of confidence (level of trust in vaccine or provider), complacency (do not perceive a need for a vaccine, do not value the vaccine), and convenience (access)"[24]. Despite being recognized as one of the most successful public health measures, vaccination is perceived as unsafe and unnecessary by a sub-set of the population. The attitude of vaccines hesitancy is one that can lead to adults refusing vaccinations altogether[25].
Expected Approximate Monetary Range of Grant Applications:	Individual projects of all scope and size will be considered. For instance, small-scale single-institution initiatives may submit grant requests ranging from $20,000 to $150,000. Large-scale multi-country collaborative projects may request grants of up to $750,000. The total available budget related to this RFP is $750,000. The amount of the grant Pfizer will be prepared to fund for any project will depend upon the external review panel's evaluation of the proposal and costs involved, and will be stated clearly in the approval notification.
Key Dates:	RFP release date: 15th February 2018 LOI due date: 12th April 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of LOIs by External Review Panel: May 2018 Anticipated LOI Notification Date: End May 2018 Full Proposal Deadline: *18 July 2018 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of Full Proposals by External Review Panel: Early September 2018 Anticipated Full Proposal Notification Date: Mid-September 2018 Grants distributed following execution of fully signed Letter of Agreement Period of Performance: October 2018 to October 2020

How to Submit:	Please go to www.cybergrants.com/pfizer/loi and sign in. First-time users should click "REGISTER NOW". Select the following Area of Interest: Immunisation in Inflammatory Conditions Requirements for submission: Complete all required sections of the online application and upload the completed LOI template (see Appendix). **Please note that all applications must be submitted in English.** If you encounter any technical difficulties with the website, please click the "Need Support?" link at the bottom of the page. **IMPORTANT:** Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.
Questions:	If you have questions regarding this RFP, please direct them in writing to the Grant Officer, Jo Harbron(jo.harbron@pfizer.com), with the subject line "Immunizations in immune-mediated inflammatory patients – February 2018"
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 or to make a summary presentation during the review period.

References:

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8. Abreu C, Sarmento A, Magro F. Screening, prophylaxis and counselling before the start of biological therapies: A practical approach focused on IBD patients. Digestive and Liver Disease 2017 Dec;49(12):1289-1297

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14. The Australian Immunisation Handbook (available at http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home~handbook10part3~handbook10-3-3#3-3-3)

15. The New Zealand Immunisation Handbook (available at https://www.health.govt.nz/publication/immunisation-handbook-2017)

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IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Independent Grants for Learning & Change (IGLC), as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click **here** to review these terms and conditions.

Appendix: Letter of Intent Submission Guidance

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. Note there is a 3-page limit in the main section of the LOI. ***LOIs not meeting these standards will not be reviewed.*** *It is helpful to include a header on each page listing the requesting organization.*

LOIs should include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Project Classification
   1. There are multiple project types that are eligible for funding through this RFP. Please indicate which of the following best represents your project. More information on these classifications can be found in the Decision Matrix posted on the Tips & Templates tab the IGLC website.
      - Dissemination and Implementation (D&I) Research
      - Quality Improvement
      - Education or Educational research
   2. Background Information
      - It is expected that D&I research projects follow generally accepted principles. For all research projects the institution(s) must agree to assume all responsibilities as sponsor of the study as outlined in the proposal. These are listed in the RFP Terms and Conditions (specifically, term #9).
        - At the time of approval of a full proposal, applicants will be required to sign a research contract, submit IRB approval and a research protocol.
      - Quality improvement projects should be described in terms of generally accepted principles of improvement science such as those described by the IHI model for improvement or LEAN.
        - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.
      - Educational projects should be planned using generally accepted principals of adult learning. More information on principals of learning and behavior change for health professionals can be found at www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf.
        - At the time of approval of a full proposal, applicants will be required to sign a letter of agreement.

C. Goal and Objectives
   1. 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).
   2. 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.

D. Assessment of Need for the Project
   1. 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.

E. Target Audience

1. 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

F. Project Design and Methods

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

G. Innovation

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.
2. 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.

H. Evaluation and Outcomes

1. 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.
2. Quantify the amount of change expected from this project in terms of your target audience.
3. Describe how the project outcomes will be broadly disseminated.

I. Anticipated Project Timeline

J. Requested Budget

1. A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.
2. The budget amount requested must be in U.S. dollars (USD).
3. While estimating your budget please keep the following items in mind:
    - Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.
    - The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.
    - It should be noted that grants awarded through IGLC cannot be used to purchase therapeutic agents (prescription or non-prescription).

- Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects.

K. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize it in within the page limitations.

Organizational Detail (not to exceed 1 page)

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. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.

Please note that any project partners listed in this section should also be listed within the online system. Tax-IDs of partner organizations will be requested when entering this information. If a partnership is only proposed, please indicate the nature of the relationship in the Organizational Detail section of your LOI.

LOIs should be single-spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and a 1-page limit for organizational detail. If extensive, references may be included on 1 additional page. **Final submissions should not exceed 5 pages in total** (3 pages for the main section, 1 page for organizational detail, and 1 page for references).

All required sections should be combined in one document (MS Word or Adobe PDF). There is no need to submit the organization detail or references in a document separate from the main section of the LOI.

Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit ***WILL BE REJECTED*** *and* ***RETURNED UNREVIEWED****.*