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:	23rd April 2018 (originally 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[6,8,9,10,11]. 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: 23rd April2018 Full proposal due date: 18th July 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5). Review of Full proposals by External Review Panel: Early September 2018 Anticipated Award Notification Date: Mid September 2018 Please note the deadline is midnight Eastern Time (New York, GMT -5). Grants distributed following execution of fully signed Letter of Agreement Period of Performance: October 2018 to October 2020

<table>
<tr><td>How to Submit:</td><td>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

Be advised the system is designed for a two-stage submission process: 1) Letter of Intent and 2) Full Proposal. However, for this RFP, we are not using a Letter of Intent. Instead, the only stage will be submission of the Full Proposal.

In the “Required Uploads” section, please follow the table below:

<table>
<tr><th>For Field Name:</th><th>Please upload:</th></tr>
<tr><td>Letter of Intent</td><td>Full Proposal (see Appendix)</td></tr>
<tr><td>LOI Additional Required Uploads</td><td>Completed budget template which is available at the following link: https://www.cybergrants.com/pfizer/docs/BudgetTemplate2017.xls</td></tr>
</table>

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.</td></tr>
<tr><td>Questions:</td><td>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 – April 2018”</td></tr>
<tr><td>Mechanism by which Applicants will be Notified:</td><td>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.</td></tr>
</table>

References:

1. El-Gabalawy H, Guenther LC, Bernstein CN. Epidemiology of immune-mediated inflammatory diseases: incidence, prevalence, natural history, and comorbidities. The Journal of Rheumatology Supplement 2010 May;85:2-10.

2. Listing J, Gerhold K, Zink A. The risk of infections associated with rheumatoid arthritis, with its comorbidity and treatment. Rheumatology (Oxford) 2013 Jan;52(1):53-61.

3. Kantsø B, Simonsen J, Hoffmann S, Valentiner-Branth P, Petersen AM,. Inflammatory Bowel Disease Patients Are at Increased Risk of Invasive Pneumococcal Disease: A Nationwide Danish Cohort Study 1977-2013. American Journal of Gastroenterology 2015 Nov;110(11):1582-7.

4. Murat Toruner, Edward V. Loftus Jr, W. Scott Harmsen, Alan R. Zinsmeister, Robert Orenstein, William J. Sandborn, Jean–Frederic Colombel. Risk Factors for Opportunistic Infections in Patients with Inflammatory Bowel Disease. Gastroenterology 2008 Apr;134(4):929-36.

5. L Winthrop, S A Novosad, J W Baddley, L Calabrese, T Chiller, P Polgreen, F Bartalesi, M Lipman, X Mariette, O Lortholary, M E Weinblatt, M Saag, J Smolen. Opportunistic infections and biologic therapies in immune-mediated inflammatory diseases: consensus recommendations for infection reporting during clinical trials and postmarketing surveillance. Annals of Rheumatic Disease 2015 Dec;74(12):2107-16.

6. Mazzola G, Macaluso FS, Adamoli L, Renna S, Cascio A, Orlando A.Diagnostic and vaccine strategies to prevent infections in patients with inflammatory bowel disease. Journal of Infection. 2017 May;74(5):433-441.

7. Falagas ME, Manta KG, Betsi GI, Pappas G. Infection-related morbidity and mortality in patients with connective tissue diseases: a systematic review. Clinical Rheumatology May 2007, Volume 26, Issue 5, pp 663–670.

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

9. Wong PKK, Bagga H, Barrett C, Hanrahan P,Johnson D, Katrib A, Leder K, Marabani M, Pentony P, Riordan J, White R, Young L. A practical approach to vaccination of patients with autoimmune inflammatory rheumatic diseases in Australia. Internal Medicine Journal. 2017 May;47(5):491-500.

10. Tanrıöver MD, Akar S, Türkçapar N, Karadağ Ö, Ertenli İ, Kiraz S. Vaccination recommendations for adult patients with rheumatic diseases. European Journal of Rheumatology 2016 Mar;3(1):29-35.

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12. S van Assen, N Agmon-Levin, Elkayam , R Cervera, M F Doran, M Dougados, P Emery, P Geborek, J P A Ioannidis, D R W Jayne, C G M Kallenberg, U Müller-Ladner, Y Shoenfeld, L Stojanovich, G Valesini, N M Wulffraat, M Bijl. EULAR recommendations for vaccination in adult patients with autoimmune inflammatory rheumatic diseases. Annals of the Rheumatic Diseases 2011;70:414-422.

13. María Dolores Sánchez-Tembleque, Carmen Corella, Jose L Pérez-Calle (ECCO) Vaccines and recommendations for their use in inflammatory bowel disease. World Journal of Gastroenterology 2013 Mar 7;19(9):1354-8.

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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20. Ledwich LJ, Harrington TM, Ayoub WT, et al. Improved influenza and pneumococcal vaccination in rheumatology patients taking immunosuppressants using an electronic health record best practice alert. Arthritis & Rheumatology 2009;61:1505Y1510.

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25. Ohid Yaqub, Sophie Castle-Clarke, Nick Sevdalis, Joanna Chataway. Attitudes to vaccination: A critical review. Social Science and Medicine. 2014 Jul;112:1-11.

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 1: Full Proposal Submission Guidance

Proposals must be single-spaced, using Calibri 12-point font and 1-inch margins. Note that the main section (section D, below) of the proposal has a 15-page limit and the organization detail (section F, below) has a 3-page limit. **Please limit the number of attachments uploaded in the system**. There is no reason to submit the organization detail (section F) as a separate document from the main section (section D) of the proposal. All proposals must follow the outline detailed below.

Proposal requirements will include the following sections:

A. Cover Page (do not exceed 1 page):

1. ***Title***: *Please include the project title and main collaborators.*
2. ***Abstract****: Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words.*

B. Table of Contents (no page limit)

C. Main Section of the proposal (not to exceed 15 pages):

1. ***Overall Goal & Objectives:*** *Describe the overall goal for this project. Describe how this goal aligns with the focus of the RFP, the goals of the applicant organizations and the proposed project. List the **key** objectives and how they are intended to address the established need for this project.*
2. **Current Assessment of need in target area**
    a. *Describe the need for this project in your target area. Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis if appropriate. Describe the need for your project in terms of "what is" versus "what should be".*
    b. *Please include 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 describes the problem) 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.*
3. ***Target Audience:*** *Describe the primary audience(s) targeted for this project.*
    a. *Describe the level of commitment from the potential participants including your plan for recruitment as necessary.*
    b. *Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.*
    c. *Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.*

4. ***Project Design and Methods:*** *Describe your project design and methods.*
    a. *Include a description of the overall strategy, methodology and analysis linking them to the goal of the project.*
    b. *Describe the way the project planned addresses the established need and produces the desired results.*
    c. *Indicate how you will determine if the target audience was fully engaged in the project.*
    d. *Include a description of the measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.*
    e. *If appropriate, show how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.*
    f. If your project includes the development of tools note if they be available publically at no cost.

5. Evaluation Design

a. In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group.
- *Identify the sources of data that you anticipate using to make the determination.*
- *Describe how you expect to collect and analyze the data.*
- *Describe how you will determine if the results evaluated are directly related to the intervention described in this proposal*

b. Quantify the amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%)

c. Describe how you plan for the project outcomes to be broadly disseminated.

6. ***Detailed Work Plan and Deliverables Schedule****: Include a narrative (which counts toward the15-page limit) describing the work plan and outlining how the project will be implemented over the time period. Using a table format (no page limit), list the deliverables and a schedule for completion of each deliverable.*

D. References (no page limit)

E. Organizational Detail (not to exceed 3 pages)

1. ***Organizational Capability****: Describe the attributes of the institution(s)/organization(s)/association(s) that will support and facilitate the execution of the project.*
2. ***Leadership and Staff Capacity****: Include the name of the person(s) responsible for this project (PI/ project lead (PL) and/or project manager). The project manager, whether a current staff member or someone to be hired, is essential to the work outlined in your proposal. Demonstrate the PI/PL and project manager's availability, commitment, and capability to plan, implement, and evaluate the proposed project; describe how the project manager will oversee the project activities, including ensuring that tasks are accomplished as planned.*

    a. List other key staff members proposed on the project (e.g., healthcare provider champion, medical advisor, statisticians, IT lead, etc.), if relevant, including their roles and expertise. Please list out key staff for each

institution/organization/association the specific role that they will undertake to meet the goals of this project.

b. *When listing staff, please include staff first name, last name, professional credentials, and Country of Residence.*

c. *<u>NOTE Regarding Proposed Speakers</u>: Pfizer IGLC shall not provide funding of CME when Pfizer has knowledge at the time of the decision to fund CME that a proposed CME faculty member has conducted a promotional speaking engagement on similar topic(s) on behalf of Pfizer in the past 12 months.*

F. Detailed Budget (Refer to/Complete **Budget Template**; no page limit for the Excel file or the narrative)**:**

1. *Upload a detailed budget, using the Excel template provided.*
   (Click here for **Budget Template;)**
   Applicants are expected to customize the budget for their proposal, adding additional details and deliverables as appropriate.
2. *Provide a written narrative in the budget description field that contains an explanation of each cost element proposed. Budget narratives should include a justification for all personnel, indicating the percentage of time allocated to the project. The budget should demonstrate appropriate and reasonable costs for project expenses.*
3. *Some examples of what awarded funds may **not** be used for are listed below:*
   - *Office equipment (e.g., furniture, computers)*
   - *Registration and travel costs for professional development meetings or courses not related to this project*
   - *Health care subsidies for individuals*
   - *Construction or renovation of facilities*
   - *Therapeutic agents (prescription or non-prescription)*
   - *Food and/or beverages for learners and/or participants in any capacity*
   - *Lobbying*

G. Staff Biosketches (no page limit):
Applicants must provide brief biosketches of all individuals listed in section F in an appendix.

H. Letter(s) of Commitment (no page limit):
Letter(s) must be provided from all organizations listed in section F documenting their support and commitment to the project. Letters should be issued from an institutional authority or
authorities and collaborators guaranteeing access, resources and personnel (as the case may be) for proposed project.

Proposals should be single-spaced using Calibri 12-point font and 1-inch margins. Please adhere to the page limits listed for each section. There is no page limit for the reference section. Tables and Figures should be included in the main section of your proposal and do count to the page count. Only sample forms or other full page documents can be included as an appendix. Please consult with the Pfizer IGLC Grant Officer before submitting such additional documents.

All required sections (aside from the budget) 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 full proposal. Budgets should be submitted in a separate excel file.