## FREQUENTLY ASKED QUESTIONS

### **Technical**

- Q How do I submit a grant request?
- When you have collected all the required information, click the "Submit Request" tab, then the Α "Start Application" button to begin the application process.
- Q Who can I contact with questions about the grant application process for help with the website?
- Α For technical assistance, please email our support desk at: CommercialComplianceNASupport@iqvia.com

For General questions about grant submissions, please use the following emails:

Janssen Biotech Inc.:

Immunology- sgallag3@its.jnj.com Oncology-OncologyGrants@its.jnj.com

Janssen Scientific Affairs: JanssenIME@its.jnj.com

Janssen Pulmonary Hypertension: <a href="mailto:rromer2@its.jnj.com">rromer2@its.jnj.com</a>

If the grant has been submitted, you will need to provide the grant ID number and the program title.

What do I do if my login and/or password don't work?

Q The login system locks users after three attempts. If this occurs, please contact use the Α

appropriate above contact emails to have your login unlocked.

Will the system time out?

Q Yes, after 60 min of inactivity the system will time out and you will need to re-log in from the Α home page. If you are in the middle of an application, navigate to My Requests to access your inprocess application. If you time out while registering, your profile will only be saved if you have completed the step to enter your email address and password.

I lost my Grant Identification Number. How can I retrieve it?

Q The Grant Management System allows you to view a dashboard that shows all your

Α organization's grant activity and status. Simply use your login and password to access the dashboard.

If you are unable to access the dashboard, please send an email with the name of the requesting organization, tax ID #, and program title to the appropriate contact above. We will send you the Grant ID Number or contact you to obtain more information.

How do I print a copy of my grant application?

Q You can print or save a PDF copy of the application from your Inbox after it has been submitted.

Α You will not be able to print a copy of an application in process. You can download blank application forms from the section called 'Resources/Forms'.

- **Q** What if I do not receive e-mail notifications?
- A Please perform the following actions:

Check SPAM and/or Junk email folders once located, right-click on the email and select the option under "Junk E-mail" to "Add Senders Domain to Safe Senders list."

Alternatively, you can also manually add support@polarismanagement.com to the safe senders list by taking these steps:

Click on Actions, then locate the "Junk E-mail Options"

Click on the tab for "Safe Senders"

Click "Add", type in Janssen RMS JanssenNoReply@grants.pharmaedgrants.com and click "OK"

- **Q** What is the maximum file size that can be uploaded?
- A The maximum single file size is 10 megabytes
- **Q** What is the difference between the My Actions and My Requests inboxes?
- A My Actions (displayed upon login) shows any grants in your queue that require immediate action i.e. unsubmitted, awaiting additional information, pending LOA. This allows you to see any tasks you need to complete when you first log into the system.

The My Requests inbox shows a history of all grants submitted by the user and location. You will only be able to act on requests you have submitted, but you will have read-only access to requests submitted by others within your organization.

- **Q** How do I set myself up for Electronic Fund Transfer?
- A Click here (link to https://www.ap.jnj.com/) to read how to sign up for EFT
- **Q** How do I set my organization up for web invoicing?
- A Click here (link to <a href="https://www.ap.jnj.com/">https://www.ap.jnj.com/</a>) to read how to sign up for Web Invoicing

### **Educational Grants**

## Registration

- **Q** How do I register my organization/institution?
- A Click on the Register button and complete the required information. Once registration is complete, you may begin to submit grant applications immediately.
- **Q** Is it possible to have more than one person register from a single organization or location?
- A Yes. Organizations are identified by their Organization Tax ID number, which is entered during the registration process. The Educational Grants System will allow you to create more than one user account for a given organization and/or location by selecting the same Organization Tax ID number / location address during the registration process.

- Q I am associated with several organizations. Do I need to register separately for each?
- A Yes. If the organizations have separate Tax ID numbers, you will need to register separately for each and provide a unique email for each.
- I work at several locations/branches within a single organization. Do I need to register separately for each location?
- A No. If all the locations/branches are under one Tax ID, they are all considered as a single registration.
- Q Is it possible for a user account (a single email identifier) to be associated with multiple organizations?
- A No, the system does not allow one user account to be associated with multiple Organization Tax ID numbers.
- **Q** What is a 'location'?
- A Some organizations have multiple locations, chapters, sites etc under the same Tax ID. Each is considered a separate location that should be registered.
- **Q** What is a third party?
- A third party is an entity that contributes to content development, certifies the activity for nonphysician audiences, or is the requesting organization's designated payee. Organizations that provide only logistics assistance are not required to register.

Third parties include any entity contributing to the content or certification of the medical education activity. Third parties could be accredited providers, medical education companies or organizations that measure educational outcomes.

All third parties must follow Janssen policies, including firewall policies.

- **Q** What if I enter false information?
- A Knowingly providing false information or failing to answer all questions truthfully and completely may be grounds for not accepting grant requests, halting existing grants, or barring organizations from future grant requests. Falsifying an application, attempting to violate the privacy of others, or attempting to compromise the operation of this system may also be criminally punishable.
- Q Why do I need to identify someone that has legal authority to sign on behalf of my organization?
- A If the organization submits a grant that is provisionally approved, the organization must have an authorized individual sign the Letter of Agreement (LOA). During the registration process, applicants must identify the individual who has the proper (legal) signing authority to execute the LOA on behalf of the organization requesting the grant.

# **Supported Activity Types**

- **Q** What are some examples of the types of grant requests Janssen does not accept?
- A See Exclusions list
- **Q** Can I request a grant for an activity that has already occurred?
- A No, Janssen does not fund activities that have already occurred.
- **Q** Does the Company give grants to individuals or private physician clinics?
- A No, Janssen cannot support grants given to an individual or a private physician clinic. Individuals cannot be designated as payees.
- **Q** Who do I contact to request funding for an exhibit or a sponsorship?
- A Such questions should be directed to the local sales representative. If you don't know who your rep is, you may call (800) 526-7736 and ask for the contact information of the sales representative that covers your area.

# **Organization Requirements**

- **Q** What types of organizations are eligible to receive an educational grant?
- A Educational grants may be awarded to for-profit, nonprofit, and 501C3 tax-exempt organizations. Educational grants for certified independent educational activities may only be provided to an accredited organization that is an academic medical center, hospital, medical society, professional association, pharmacy, nursing, governmental agency or quality organization that is directly involved w/ patient care.
  - The applicant must be an accredited provider that is engaged in or represents healthcare professionals who provide direct patient care.
- **Q** My organization is a medical education and communication company (MECC) that is an ACCME-accredited provider of CME. Can we submit an educational grant application to Janssen?
- A Yes.
- **Q** What are the basic requirements for a fellowship support request?
- A Janssen may provide support to teaching institutions for their medical education programs by sponsoring fellowships. The terms of the fellowship must be clearly documented in a written agreement. Requests must include the selection criteria and state that there is a bona fide selection committee in place to select the final recipient. Grants must be provided to the teaching institutions and not to individual fellows.
- **Q** For which type of conferences are Fellowship travel requests considered?
- A The subject of the educational activity must generally fall within a therapeutic area of interest to the Company. Grants must be provided to the teaching institutions and not to individual fellows

#### **General Submission FAQs**

- **Q** What are the requirements for grant submissions?
- A For information on requirements for specific grant types please refer to the Requirements for Grant Requests section on our company website
- Q What documents/information do I need to have available when I initiate a new grant request?
- A For information on requirements for specific grant types please refer to the Requirements for Grant Requests section on our company website
- Q Do I need to attach the SIGNED Certificate of Separation? Where can I find a blank one?
- A All educational grant applications are REQUIRED to have a SIGNED copy of the Janssen Certificate of Separation (COS). If you are working with a Third Party, that group also MUST submit a signed COS. Please visit the respective education grant pages to view the Certificate of Separation.
- **Q** Can I complete part of the grant request and return to it later?
- A Yes. If you are unable to complete your grant request in one sitting, you may save the request and come back to it later by clicking < Save & Continue Later> at the bottom of the page. At any time before the submission of a grant request, you will have the opportunity to come back and make changes to the request.
- **Q** Can I submit one application for multiple activities?
- A Yes, one application can be submitted for a related series of activities such as a grand round series, or a multiple component grant (live event with enduring activities).
- **Q** Can I submit more than one application at a time?
- A Yes. Organizations may submit multiple requests into the system. Each must be treated as a separate application.
- Q My activity falls within 2 or more therapeutic areas. How should I submit the application?
- A Please refer to Janssen Areas of Interest as guidance.
- **Q** Can I fax or mail in my request?
- A No. We no longer accept fax or emailed requests. Applications must be submitted online through the Grant Management System.
- Q Can my local sales representative assist me with completing the application process or apprise me of the status?
- A No. Only the Janssen Grant Office may assist you with your request. No other Janssen personnel may assist you with your request. Submission of your grant request by any Janssen personnel will lead to an automatic rejection of the request.

#### **Grant Process FAQs**

- **Q** What is the required lead time for submitting a request?
- A Please refer to Janssen Grant Application Windows for guidance on timing for submissions.
- **Q** How do I determine when to apply?
- A Please see the organization supporting the therapeutic area you are interested in submitting a grant for specific submission information.
- Q What will happen to the online submission system during the months that you are not accepting applications?
- A You will only be able to access the submission page during the months that we are accepting applications. However, the remainder of the information on our company website (eg, guidelines, forms, FAQs) will be available all year round.
- Q What if I miss the application window? Can I apply late or by another method?
- **A** Late requests will not be accepted.
- **Q** How will I know if my grant request was successfully submitted?
- A You will receive a confirmation email with the Grant Identification Number assigned to your request once the grant has been submitted.
  - You may also check in My Requests on the grants portal to check the status.
- **Q** How can I check the status of my grant request?
- A Log in to the grants portal to access "My Requests" on your homepage. The Inbox will contain a list of all grants and the status of each.
  - You may check the status of your request by clicking on "My Requests" in the grants portal
- **Q** How long will it take to receive a decision?
- A Please refer to the Application Notification Grid to view when notifications are sent following application periods. Grants are not considered fully approved until a Letter of Agreement is signed by all parties.
- **Q** How will I know if my request has been approved or denied?
- A You will receive an email notification once a decision has been reached on your funding request. You can check the status of your grant online in "My Requests"
- **Q** What if I have my own Letter of Agreement?
- A Janssen utilizes its own Letter of Agreement (LOA) that has been vetted by the Company's Legal Dept. Applicants are required to utilize only this LOA.

### **Application FAQs**

- **Q** What if my descriptions, agenda, budget etc. do not fit into the allotted space?
- A You will have the opportunity to upload supporting documentation at the end of the Grant Request Form.
- **Q** What happens if my third parties or authorized signers do not show up in the drop-down windows during the request?
- A The third-party organization must come into the system and verify their registration before they appear on the verified list. When you enter the contact information for that third party, they will receive an auto-generated email inviting them to register within the system.
- Q I am having trouble attaching multiple documents. How can I submit the information?
- A The system allows a maximum of six (6) attachments per application. There are not any limitations on use of special characters. Users can paste text into most fields in the system. Documents can be any basic document types (i.e. Word (.doc), Excel (.xls), PowerPoint (.ppt), and/or PDF (.pdf), images, text files, etc.). Zip files and special characters (& / \* etc.) are not permitted.
- Q In the required budget template, should I provide the entire activity budget or just the portion for which I am requesting funding from The Company?
- A We require that the overall expenses of the program (Total Program Costs columns), as well as the requested funds (Requested Funding from Janssen columns) is captured in the budget form in the application
- **Q** What if my request is missing some necessary information? Will the company contact me?
- A Submissions that are missing required documentation will be rejected and you will be notified. If any documentation requires clarification or additional detail, we will contact you. Requests for additional documentation must be completed within 10 business days.
- Q What is a 'Request for Additional Information' and how much time do I have to provide the requested information?
- A Request for Additional Information (RAI) is made when more information is needed to consider your grant request. The request will be sent via email. Please log in and navigate to your request. Only the fields that have been selected for more information will open up to edit. Once you have completed the information, please re-submit. OPCO will follow-up on the original request via e-mail after 10 business days. If the requesting organization has not received all necessary information within 30 business days of the follow-up request, the grant request will be declined.
- **Q** Can I resubmit if my grant request is denied?
- A Your rejection notification will indicate whether the request is eligible for resubmission.

### **Approved Grant FAQs**

- Q If my grant request is approved and the program takes place shortly after the notification period, will I receive my payment in time for the program?
- A If your grant request is approved, we will do our best to process your contract and payment in a timely fashion but cannot guarantee that you will receive payment prior to your activity date.
- **Q** Will my funding to my organization be made public?
- A If your grant is accepted, Janssen reserves the right to post the information regarding funding under this agreement on a publicly accessible web site. This includes the identity of the recipient, the monetary value of the funding, the purposes for such funding, and other information as the Company determines appropriate. This information is available in to view Transparency Report.
- **Q** What language should we use in our program materials/signage to recognize Janssen support of our educational program?
- A Refer to the Letter of Agreement for appropriate verbiage.
- **Q** How do I request a logo to acknowledge your company's support of a program?
- A To request a copy of our corporate logo, please contact the appropriate organization listed above You will need to provide your grant identification number and the email address on file with your application.
- **Q** How do I access and manage my grants?
- A Log in to the grants portal to access "My Requests" on your homepage and take the appropriate action.
- Q Can funding be transferred to a similar or different program if the original program is cancelled?
- A No. A new grant request for the revised activity must be submitted. Funds provided for activities that are cancelled or changed must be returned to Janssen
- **Q** What is Manage Activities?
- A Manage Activities is a process through which applicants can view the payment milestones associated with a grant and notify the Company of any updates or changes to the program(s).
- **Q** What is a Scope Change?
- A change in the scope of a program requires completion of a Change of Scope Form. These changes can include significant change in activity timelines, the number and/or types of activities, or changes in budget requirements. Scope change requests must be reviewed by the Janssen Grant Review Committee. The Committee may choose to approve the scope change or deny and request a return of funds.
- Q Must I submit a new request if the program dates and/or speaker information have been modified from the original?

- A No. However, the date change must be updated in the grant through the "Amendment Process" link. The rescheduled activity date must be within 12 months of the signed agreement. If the date is beyond 12 months of LOA signing, a scope change form is required
- **Q** How do I submit the results of my educational outcomes assessment(s)?
- A Preliminary Outcomes Reports can be uploaded at the time of Reconciliation. Final Reports can be emailed to the Grants Office when available.
- **Q** What information is required when submitting the activity reconciliation?
- A the completion of the funded activity, organizations are required to submit information detailing the audience reach, use of funds, and other information to verify the grant funding was used in alignment with the approved application.
- **Q** Am I required to reconcile my budget and return any unused funds?
- A Yes, to the extent that any of the funds are not used for the activity as defined in the written agreement, the provider must return any unused or excess funds to Janssen within 6 months following the completion of the activity.

# **GLOSSARY OF TERMS**

**Accreditation:** The decision by the ACCME, or a recognized state medical society, that an organization has met the requirements for a CME provider as outlined by the ACCME. The standard term of accreditation is four years.

Accreditation Council for Continuing Medical Education (ACCME): The ACCME sets the standards for the accreditation of all providers of CME activities. The ACCME has two major functions: the accreditation of providers whose CME activities attract a national audience and the recognition of state or territorial medical societies to accredit providers whose audiences for its CME activities are primarily from that state/territory and contiguous states/territories. The ACCME's seven member organizations are the American Board of Medical Specialties (ABMS), the American Hospital Association (AHA), the American Medical Association (AMA), the Association of American Medical Colleges (AAMC), and the Association for Hospital Medical Education (AHME), the Council of Medical Specialty Societies (CMSS), and the Federation of State Medical Boards of the US, Inc., (FSMB).

**Accreditation Status:** The standings of accreditation offered and made by the ACCME, or a state medical society, to accredited providers. They include accreditation with commendation, accreditation, probationary accreditation, provisional accreditation and non-accreditation.

**Accredited Provider:** Accredited Providers submitting grant applications must be directly involved in patient care (i.e. Academic Institution /Medical Center (non-gov't), Hospital or Health Care Delivery System, Medical/ Professional Society, Publishing/Educational Company etc) Medical Education/Communications Companies cannot be the primary applicant (even if they are accredited).

**Acknowledgment of Commercial Support:** May state the name, mission, and areas of clinical involvement of the company or institution and may include corporate logos and slogans, if they are not product/promotional in nature.

Attestations: For educational grant requests only: Statements used as Attestations are replacing statements that were previously submitted in the Letter of Request and Credentialing Form. The statements pertain to the accuracy of the information that is contained within the Grant Application The grant applicant reviews the attestations and, if applicable, checks the box that they are true and accurate.

**Authorized Signer/E-Signature:** For educational grant requests only: The person within the organization applying for funding that has the legal/proper signing authority to sign off on the Letter of Agreement for an approved activity. Charitable contributions will still require a hard copy signature.

**Certification of Separation:** This document certifies that departments /companies receiving educational grants from Janssen are not affiliated with departments that may provide promotional medical education. Also known as a "Firewall Certificate". This document is required for CME/CE and non-CE educational grant requests.

**Commercial Interest:** Any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies. The

ACCME does not consider providers of clinical service directly to patients to be commercial interests. The ACCME considers the following types of organizations eligible for accreditation and free to control the content of CME: Liability insurance providers; Health insurance providers; Group medical practices; For-profit hospitals; For-profit rehabilitation centers; and For-profit nursing homes.

**Commercial Support:** The provision of financial, or in-kind, contributions given by a commercial interest, which is used to pay all or part of the costs of a CME activity.

**Conflict of Interest:** Circumstances create a conflict of interest when an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship. The ACCME considers "content of CME about the products or services of that commercial interest" to include content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

**Continuing Medical Education (CME):** Continuing medical education consists of educational activities, which serve to maintain, develop, or increase the knowledge, skills, and professional performance, and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.

Not all continuing education activities in which physicians engage are considered CME. Physicians may participate in worthwhile continuing. educational activities that are not related directly to their professional work, and these activities are not CME. Continuing education activities, which respond to a physician's non-professional educational need or interest, such as personal financial planning, or appreciation of literature or music, are not CME.

**Co-sponsored Activity:** A CME activity presented by two or more accredited providers. One institution must take responsibility for the activity.

**Educational Partner:** A third party that provides support to a primary applicant, most commonly for CME/CE-certified educational activities. The Educational Partner may be responsible for content development and/or may provide certification for the activity for health care professionals OTHER THAN physicians (e.g. nursing credit, pharmacy credit), or can be the requesting organizations designated payee. (ALSO SEE THIRD PARTY)

**Enduring Materials:** Enduring materials are printed, recorded or computer assisted instructional materials which may be used over time at various locations and which in themselves constitute a planned CME activity. Examples of such materials for independent physician learning include: programmed texts, audiotapes, videotapes and computer-assisted instruction materials, which are used alone or in combination with written materials. Books, journals (unless specifically designated) and manuals are not classified as enduring materials.

**Joint Sponsorship:** Sponsorship of a CME activity by two or more institutions/organizations when one of the institutions/organizations is accredited. The accredited provider must take responsibility for the

content of a CME activity when it is presented in cooperation with a non-accredited institution or organization and must use the appropriate accreditation statement.

**Jointly Sponsored Activity:** An activity planned and implemented by one ACCM E or state medical society accredited provider working in partnership with one or more non-accredited entities. The accredited provider must ensure compliance with the ACCME Essential Areas and Policies.

**Learning/Educational Objectives:** Statements that clearly describe what the learner will be able to know or do after participating in the CME activity. The statements should result from the needs assessment data.

Medical Education /Communications Company (MECC): MECCs may serve as Educational Partners/Third Parties to Accredited Providers that submit educational grant applications. They may be involved in content development, logistical planning, etc. The MECC CANNOT be the primary applicant for certified medical education programs; applications must be submitted by CME/CE providers. Third Parties such as MECCs must register within the system and can be associated with a CME/CE provider registrant at the time the CME/CE provider registers or at the time they submit an application for funding. Third Parties will be notified when they are required to register within the system.

**Needs Assessment:** A document that provides identification and analysis of current data that reflects the need for a particular CME activity. The needs assessment should utilize information from surveys of the potential learners, evaluations from previous CME activities, literature searches, needed health outcomes, identified new skills, etc. Needs assessments provide the basis for developing learner objectives for the CME activity.

**Provider:** See Accredited Provider.

Relevant Financial Relationships: Financial relationships with commercial interest in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines 'relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

**Sponsor:** See Provider

**Supporter:** See Commercial Supporter

**Third Party:** A Third Party is an organization that provides support to a primary applicant, most commonly for CME/CE-certified educational activities. Third Parties may be responsible for content development and/or may provide certification for the activity for health care professionals OTHER THAN physicians (e.g. nursing credit, pharmacy credit), or can be the requesting organizations designated payee. (ALSO SEE EDUCATIONAL PARTNER)

**Validation of Content and Quality:** All recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

**Validation of Scientific Integrity:** All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.