



# Merz Grants and Giving FAQs

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## General Grant Questions

### **Q: What type of grants/giving does Merz support?**

**A:** Merz offers funding to support various commercial, educational, and charitable requests. Merz also offers funding for Investigator Initiated Studies.

- **Commercial Support**
  - Sponsorships of healthcare-related programs such as patient education, exhibit opportunities and levels of sponsorship for scientific and trade meetings.
- **Educational Grants (Accredited)**
  - Educational programs for healthcare practitioners that provide continuing education credits to participants (CME, CE, CNE, ACPE, etc.).
  - Merz North America supports both certified and non-certified programs with independent medical educational grants.
- **Educational Support (Non-accredited)**
  - Support for general education within Residency and Fellowship programs
  - Scholarly support for medical students, residents and fellows to attend medical and scientific conferences within their field.
  - Non-accredited scientific educational programs and meetings.
- **Charitable Giving**
  - Merz provides domestic charitable support. Merz participates in philanthropic endeavors which may include but are not limited to:
    - Charitable contributions related to our therapeutic areas of interest
    - Charitable contributions to support healthcare-related activities of a registered tax-exempt organization.
    - Hospitals, academic institutions, managed care organizations, non-profit and professional societies and 501(c)(3), 501(c)(4), and 501(c)(6) organizations are eligible to submit requests at least 60 days prior to the activity date.
- **Investigator Initiated Study**
  - While Merz conducts its own clinical studies related to Merz products, on occasion a doctor or facility will request funding for a study that evaluates Merz product(s) in a real-world scenario. In such a study, the investigator writes, conducts, analyzes, and reports the data, and, as such, the investigator assumes all responsibilities as the *sponsor* of the study, as defined by regulation. Upon review of the application and the study protocol, Merz may agree to fund such a study by providing product-in-kind (drug or device), and/or financial or other study-related aid. Merz is not responsible for the oversight or management of the study.

The following types of organizations are eligible to apply for all grants: healthcare practitioners, hospitals, academic medical center, professional societies and associations, patient societies and associations, as well as other institutions specializing in specific healthcare-related disciplines.



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## **Q: What are some benefits of online application?**

**A:** Online application allows for greater application flexibility and visibility of the grant process:

- You will have the ability to work on a proposal and save it in the system until you are ready to submit.
- You will have the ability to track the status of your proposal throughout the grant approval process.
- You will be able to track milestones.
- You can assign yourself tasks.

## **Q: Who can apply for a grant?**

**A:** Merz accepts requests from:

- Accredited Health Care Providers (HCPs)
- Medical or Professional Associations
- Community Health Centers
- Patient Associations or Advocacy Groups
- Universities or Colleges
- Medical Education Companies
- Other groups who have the potential to provide high-quality medical education

*Merz will NOT provide medical education grants for the following types of funding requests:*

- Grants that are intended to directly and commercially promote Merz products
- Funding for events or activities that have already occurred
- Service contracts
- Entertainment (e.g., holiday parties, recognition / retirement dinners, etc.)
- Capital or operating expenses (e.g., office equipment, staff, computer hardware / software, medical library resources, etc.)
- Grants that seek funding only for promotional exhibits or display space (although Merz does itself participate in such events, the sponsorship process is separate from the Merz Grants process)
- Personal or practice development programs, unless such programs foster increased understanding of clinical, scientific or healthcare issues
- Travel fellowships

## **Q. How long does the application process take?**

**A:** You should allow a minimum of 4-8 weeks for the grant to process. General approval can be anywhere from 2-4 weeks followed by contract review and



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processing that may take an additional 2-4 weeks. Review of applications for IIS grants may take longer (up to 10 weeks).

## **Q. How do I apply for a grant?**

**A:** [To apply for a grant via our Grants and Giving portal, click here.](#) Additional information about Merz's Grants & Giving program can be found on the Merz North America website at [www.merzusa.com](http://www.merzusa.com).

- When you visit the portal for the first time, you will be asked to register.
- You will be sent a password within 5 minutes of registering.
- You may begin your application anytime after you sign in in by selecting the type of grant for which you would like to apply. You will be automatically taken to that category and asked to answer a series of questions.
- You will be asked to upload supplemental documents such as a signed letter or summary (on your institutional letterhead) for both the grant and any product requests or a recently signed W-9.

## **Q: What information do I need to provide when applying for a grant?**

**A:** You will need to provide information via online application about your organization or practice and the event or activity you would like Merz to support. Be prepared to provide supporting materials such as:

- A signed letter or summary on your institutional letterhead describing the anticipated activity. You will be asked to include details such as:
  - Objectives
  - Intended audience
  - Event details
  - Budget (if applicable)
  - Study concept or full proposal
  - Request for product
- Copy of a Medical License when requesting product and a recently signed W-9.

## **Q. Who reviews and approves grant applications?**

**A:** Merz's internal Grant Committee reviews all applications.

## **Q How do I return unused grant product?**

**A:** When the grant includes product-in-kind, Merz's contract requires that product not used for the purpose requested either be returned to Merz or destroyed. Email the grant administrator at [grants.us@merz.com](mailto:grants.us@merz.com). Include the product description, number



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of the product returned and the lot #. You will be contacted by Customer Service. They will provide you with instructions for destruction, or a return authorization number and date of UPS pick up.

**Q: How do I check the status of my application with Merz?**

**A: Please see the definition of the stages of review below.**

- **Draft** - Stage of application before requestor has submitted application
- **Draft Submitted** - Application has been submitted by requestor and is being prepared by the Grant Administrator for Grant Committee Review
- **In Review** - Application has been processed and is queued for review by the Grant Committee. An email will be sent to the requestor at this stage.
- **Approve Pending Contract** - Grant has been approved by Merz's Grant Committee and the contract is routing for signature to the requestor and the appropriate Merz Representative. An email including a letter of agreement or contract will be sent to the requestor from [merz-\(grant number\)-us](mailto:merz-(grant number)-us).
- **Awarded** - Fulfillment has begun. This occurs in the form of ordering product or requesting fulfillment of funding depending on letter of agreement or contract details.
- **Decline** - An email will be sent to the requestor if Merz is unable to support the request.



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## How to Submit a Commercial Sponsorship/Exhibit Request

**Step 1: Go to log on page and register** using the link that best describes your status. For example: Click on HCP, For profit organization or non profit organization. You will be emailed a password in approximately 5 minutes.

**Step 2: Sign in and create and change your password.** Then select the category of your submission.

**Step 3: Complete the online application.** You will be asked to upload supplemental documents such as:

- Sponsorship Brochures
- Faculty List
- Agenda
- Current W-9
- A letter describing the anticipated activity (objectives, intended audience, event details and budget, if applicable) signed on organization letterhead.

Once submitted you will notified via email when your application has been received.

**Step 4: The Review Process.** After the application is assessed you will receive a denial, approval or request for more information.

**Step 5: Contracting and Support.** If your application is approved you will be asked to complete the contracting process. You will receive a letter of agreement via email from Merz with an assigned grant number from [merz-\(request\\_number\)-us@secure@signority.com](mailto:merz-(request_number)-us@secure@signority.com). Any approved support will begin once all contracting and required documentation is complete under the terms of your agreement.

Once your application is submitted, you can check the status of your submission by logging into your account and selecting "My Application." Please note that our evaluation can take from 4-8 weeks depending upon complexity and applicability (longer for IIS applications).



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## How to Submit an Educational Grant Request

**Step 1: Go to log on page and register** using the link that best describes your status. For example: Click on HCP, For profit organization or non-profit organization. You will be emailed a password in approximately 5 minutes.

**Step 2: Sign in and create and change your password.** Then select the category of your submission.

**Step 3: Complete the online application.** You will be asked to upload supplemental documents such as:

- Current W-9
- A letter describing the anticipated activity (objectives, intended audience, event details, and budget, if applicable) signed on organization letterhead.
- Product request letter signed and on organization letterhead if product is being requested
- Faculty List if applicable
- Agenda

Once submitted you will notified via email when your application has been received.

**Step 4: The Review Process.** After the grant is assessed you will receive a denial, approval or request for more information.

**Step 5: Contracting and Support.** If your grant is approved you will be asked to complete the contracting process with our legal department. You will receive a letter of agreement from Merz via email from [merz -\(grant number\)-us \[secure@signority.com\]](mailto:merz-(grant_number)-us[secure@signority.com]). Any approved support will begin once all contracting and required documentation is complete under the terms of your agreement.

Once your application is submitted, you can check the status of your submission by logging into your account and selecting “My Application.” Please note that our evaluation can take from 4-8 weeks depending upon complexity and applicability (longer for IIS applications).



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## How to Submit a Charitable Giving Request

**Step 1: Go to log on page and register** using the link that best describes your status. For example: Click on: HCP, For profit organization or non profit organization. You will be emailed a password in approximately 5 minutes.

**Step 2: Sign in and create and change your password.** Then select the category of your submission.

**Step 3: Complete the online application.** You will be asked to upload supplemental documents such as:

- Documentation showing 501(c)(3), 501(c)(4), and 501(c)(6) status
- A letter describing the anticipated activity (objectives, intended audience, event details, and budget, if applicable) signed and on organization letterhead.
- Product request letter signed and on organization letter head if product is being requested.
- Faculty List if applicable
- Agenda

You will notified via email when your application has been received.

**Step 4: The Review Process.** After the grant is assessed you will receive a denial, approval or request for more information.

**Step 5: Contracting and Support.** If your grant is approved you will be asked to complete the contracting process with our legal department. You will receive a letter of agreement from Merz via email from [merz-\(grant\\_number\)-us\[secure@signority.com\]](mailto:merz-(grant_number)-us[secure@signority.com]). Any approved support will begin once all contracting and required documentation is complete under the terms of your agreement.

Once your application is submitted, you can check the status of your submission by logging into your account and selecting "My Application." Please note that our evaluation can take from 4-8 weeks depending upon complexity and applicability (longer for IIS applications).





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## How to Submit a Request for Funding of an Investigator Initiated Study (IIS)

### What to expect when you submit an IIS application online with the Merz Grant System.

We know submitting a Full Proposal is a large investment of your time. As a courtesy to you, we ask for Concept Synopsis only first. We will only ask for a Full Proposal after Merz has approved the Concept Synopsis. The online system will ask a series of questions and stop you at the Concept level. Upon request for Full Proposal the portal will open the application tabs with additional questions for you to answer.

IIR Concept Form: Online submission of the Investigator Initiated Research Concept Form will capture:

- Full contact information
- Curriculum vitae
- Protocol/Study Title
- Purpose/Hypothesis
- Primary Outcome
- Sample Size
- Inclusion Criteria
- Exclusion Criteria
- Brief Study Design
- Brief Statistical Analysis Plan
- Study Duration
- Estimated Budget

IIR Full Proposal Application Form: Online submission of the Investigator Initiated Research Full Proposal Application Form will capture information already provided in the IIS Concept Application, and will request more detail around:

- Study Design/Treatment Method
- Rationale/Hypothesis
- Primary/Secondary Objectives
- Objectives/Endpoints
- Eligibility Criteria
- Publication Plan Statistical Plan
- References

You will be able to work on a proposal and save it in the system until you are ready to submit. You will also be able to track the status of your proposal throughout the grant approval process.

### Application Step-by-Step

**Step 1: Go to log on page and register** using the link that best describes your status. For example: Click on HCP, For profit organization or non profit organization. You will be emailed a password in approximately 5 minutes.



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**Step 2: Sign in and create and change your password.** Then select the category of your **submission**.

**Step 3: Select IIS Application.** You will be asked to upload supplemental documents such as:

- Curriculum vitae
- Budget

Once submitted you will be notified via email when your application has been received.

**Step 4: The Review Process.** After the Concept Synopsis is assessed you will receive either a request for more information, a denial, or an invitation for Application of Full Proposal via email. Please proceed to your applicant portal to complete the Full Proposal at this time. You will have 21 days to submit a Full Proposal for review. If a Full Proposal is received beyond the 21 day timeline, the proposal will go back into the IIS queue for reconsideration.

**Step 5: Contracting and Support.** If your Study Proposal is approved you will be asked to complete the contracting process. You will receive a contract via email from [merz-\(study number\)-us\\_secure@signority.com](mailto:merz-(study number)-us_secure@signority.com). Any approved support will begin once all contracting and required documentation is complete under the terms of your agreement.

**Step 6: Study and Publication Tracking.** Throughout your study, you will be asked to provide regular updates on your progress, as well as any required regulatory reports. You will also be asked to provide updates on publication status once your study is closed. You can find a progress report under the document icon on your home page.

- Download the document and save it to your computer
- Fill out the document and save
- Send an email the document to the Grant Administrator at [grants.us@merz.com](mailto:grants.us@merz.com). Your Milestone will then be updated in the system.

Once your application is submitted, you can check the status of your submission by logging into your account, and selecting "My Application". Please note that the IIS evaluation process can take as long as 10 weeks.



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## Information about Investigator Initiated Studies (IIS)

### **Q:** How do I submit a request to fund an Investigator Initiated Study (IIS)?

**A:** The system is set up so that you can request a concept review without having to submit a Full Proposal. When you first go on the system, you can submit either a Concept or a Full Proposal in the online system. The system will guide you through a series of information fields that will help the Review Committee review your proposal at each phase (Concept or Full Proposal). Initially, you will be asked to submit a Study Concept to ensure that the proposed research is of strategic and scientific interest to Merz. If the Concept is accepted you will be invited to submit a Full Proposal. We will request Full Proposal via an email instructing you to return to the site to complete additional information fields.

Start by:

- Go to the application link [insert hyperlink or URL here].
- Select IIS [put actual name of the link or button they need to select].
- Follow the prompts and begin your application by providing a brief overview (Concept) of your study.
- Upload a current CV as directed by the CV tab.
- You will be notified via email when your Concept has been reviewed. If accepted, we will ask for a Full Proposal.
- You will be able to return to your application at any time, either by clicking on the portal link in the email sent to you or going directly to the sign in page.
- You may check the status of your application via the Grants & Giving portal link at any time.
- If your Full Proposal is accepted, you will be asked to complete the contracting process. This will come to you in the form of an email. Approved support for your study will begin when an executed contract has been completed and all required documentation has been received.
- During the study you will be asked to provide regular progress updates and any required regulatory reports. You will also be asked to update publication status once your study is closed.
- To check the status of your submission, log into your account, and select "My Application." There will be milestone reminder tabs along with status updates for your convenience.
- Please note that our evaluation can take a few days, weeks or months depending upon the complexity and applicability. In general, it may take up to up to 3 months to complete a full IIS submission, review and formal contracting.



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**Q: What information detail will I be expected to provide when I submit an IIS grant request online?**

**A:** Online submission of the Investigator Initiated Research Concept Form will capture:

- Full contact information
- Curriculum vitae
- Protocol/Study Title
- Purpose/Hypothesis
- Primary Outcome
- Sample Size
- Inclusion Criteria
- Exclusion Criteria
- Brief Study Design
- Brief Statistical Analysis Plan
- Study Duration
- Estimated Budget

Online submission of the Investigator Initiated Full Submission Application Form will capture:

- Study Design/Treatment Method
- Rationale/Hypothesis
- Primary/Secondary Objectives
- Objectives/Endpoints
- Eligibility Criteria
- Detailed Budget
- Budget line items to consider at fair market value may include the following:
  - Institutional Overhead
  - Personnel wages
  - IRB fees
  - Subject recruitment, reimbursement, etc.
  - Supplies
  - Data collection/management
  - Publication writing assistance, travel, etc.
- Publication Plan Statistical Plan
- References

**Q: How do I request product-in-kind for my study?**

**A:** After the IIS is approved and the contract is fully executed, you may request product by downloading the Request for Shipment of Study Product document from the document icon on the applicant portal at [merz.smartsimple.com](https://merz.smartsimple.com). Note that Merz will not “automatically” ship product just because the contract is signed. Once completed send the document to the grant administrator at [grants.us@merz.com](mailto:grants.us@merz.com).



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**Q: How do I report study updates and milestone attainment?**

**A:** You may report milestones by downloading the request document from the Progress report/Milestone icon within the Merz Grants and Giving applicant portal. Once completed send to the Grant Administrator at [grants.us@merz.com](mailto:grants.us@merz.com).

**Q: Can I submit a grant request for support of an event or IIS that has already begun or concluded?**

**A:** No, Merz will not review or approve grant requests for studies that have already begun or concluded.



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## Disclosure of Financial Support

**Q: Why does Merz disclose financial support for organizations and activities?**

**A:** Section 6002 of the Affordable Care Act required the Centers for Medicare and Medicaid Services (CMS) to establish a transparency program. Section 6002 is also known as the “Physician Sunshine Act” and the U.S. government has rebranded it as the “Open Payments” System. Open Payments is a federal program intended to increase public awareness of financial relationships between drug and device manufacturers and the health care providers who participate in Federally-reimbursed programs such as Medicare and Medicaid.

**Q: Does Merz report grants in Open Payments?**

**A:** Yes. Open Payments requires “Applicable Manufacturers” of covered drugs, devices, biologics, and medical supplies to report payments or other transfers of value they make to physicians and teaching hospitals to CMS. Merz is an “applicable manufacturer.”

**Q: How are payments reported?**

**A:** Merz started collecting data on August 1, 2013. In each subsequent calendar year, Merz will submit a report to CMS detailing every “payment and other transfer of value” that we have made to physicians and teaching hospitals. CMS will aggregate the data and publish it on a public website.

**Q: What payments will Merz North America report?**

**A:** Merz will report all payments and “transfers of value” made directly to physicians and teaching hospitals, whether the payment is made with cash or cash equivalent, in-kind items, or services. In addition, Merz must report certain indirect payments and transfers of value, such as donations of speaker’s fees to a charity at the request of or on behalf of a physician.

**Q: How will Merz describe Payments and Transfers of Value?**

**A:** CMS has defined the categories that manufacturers can use to describe payments and transfers of value. Merz is required to report the reason for or “nature of” each payment, under one of the following categories:



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- Charitable contributions
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Compensation for serving as faculty or as a speaker for an unaccredited and non-accredited continuing education program
- Consulting fees
- Current or prospective ownership or investment interest
- Education
- Entertainment
- Food and Beverage
- Gifts
- Honoraria
- Research
- Royalty or license
- Space rental or facility fees (teaching hospital only)
- Travel and lodging

**Q: Will Merz report charitable contributions?**

**A:** Yes. If a physician requests a charitable contribution, Merz will report it as an indirect payment to the physician, made on behalf of the physician and not in exchange for any service or benefit. If a physician provides consulting services to an applicable manufacturer and requests that payment for the services be made to charity, this would be reported as a directed consulting fee.

### **Additional Information about the Sunshine Act**

CMS has established a public website called “National Physician Payment Transparency Program: OPEN PAYMENTS.” [To view the site, click here.](#)

This website provides helpful information including an overview of the program, a description of how the program will work and fact sheets for physicians and teaching institutions (TI). [To view Frequently Asked Questions regarding the National Physician Payment Transparency Program, click here.](#)