Crohn’s & Colitis Foundation
Entrepreneurial Investing Award

Program Guidelines

Effective December 4, 2017

Crohn’s & Colitis Foundation
National Office
Research & Scientific Programs Department
733 Third Avenue
Suite 510
New York, NY 10017

Contact:
Gerard Honig PhD
Tel: (646) 943-7479
E-mail: ghonig@crohnscolitisfoundation.org
Web site: http://www.crohnscolitisfoundation.org

MISSION:
To cure Crohn’s disease and ulcerative colitis,
and to improve the quality of life of children and
adults affected by these diseases.
# Table of Contents

<table>
<thead>
<tr>
<th>Program Policies &amp; Instructions</th>
<th>1. Overview</th>
<th>p. 1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. Funding and resources</td>
<td>p. 1</td>
</tr>
<tr>
<td></td>
<td>3. Eligibility</td>
<td>p. 1</td>
</tr>
<tr>
<td></td>
<td>4. Selection criteria</td>
<td>p. 2</td>
</tr>
<tr>
<td></td>
<td>5. Application instructions &amp; timeline</td>
<td>p. 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appendices</th>
<th>A. Letter of Intent questionnaire</th>
<th>p. 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B. Review process &amp; policies</td>
<td>p. 9</td>
</tr>
<tr>
<td></td>
<td>C. Award terms</td>
<td>p. 10</td>
</tr>
<tr>
<td></td>
<td>D. Frequently asked questions</td>
<td>p. 11</td>
</tr>
<tr>
<td></td>
<td>E. Full proposal format</td>
<td>p. 13</td>
</tr>
</tbody>
</table>

## Key Dates

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission of Letter of Intent (LOI) for consideration in upcoming review cycle</td>
<td>January 22(^{nd}) 2018</td>
</tr>
<tr>
<td>Submission of full proposal (if invited following LOI review)</td>
<td>March 12(^{th}) 2018</td>
</tr>
</tbody>
</table>
Program Policies & Instructions

1. Overview
The mission of the Crohn’s & Colitis Foundation is to cure Crohn's disease and ulcerative colitis, and to improve the quality of life of children and adults affected by these diseases. In order to pursue this mission, the Crohn’s & Colitis Foundation seeks to support and accelerate the discovery and development of research-based products with potential for positive impact for patients suffering from inflammatory bowel diseases (IBD). The Foundation hereby solicits Letters of Intent from companies and academic investigators seeking support for the discovery and development of such products. Letters of Intent will be reviewed in order to confirm that product opportunities are eligible for Foundation support.

In particular, the Crohn’s & Colitis Foundation has initiated the Entrepreneurial Investing (EI) Initiative to fund the discovery and development of products with potential for benefit in the IBD field. Funded programs may be led by companies or academic investigators. The EI Award is not a traditional research grant mechanism. Its objective is to identify and support organizations that will benefit from partnership with the Foundation in pursuit of product discovery and development. This document identifies program policies and terms, funding and resources available for awardees, eligibility, selection criteria and application procedures.

The Crohn’s & Colitis Foundation also seeks to engage with companies and investigators who are not necessarily interested in or eligible for the EI Award at this time, but who are actively seeking to discover and develop products for positive impact in the IBD field. Such companies and investigators are encouraged to submit a Letter of Intent as an initial step in the identification of Foundation resources that may be of interest, including future funding opportunities.

2. Entrepreneurial Investing Award: Funding and resources
Research & development (R&D) projects will be funded to advance the discovery or development of a specific product with potential for positive impact in the IBD field. Funded projects should be approximately 12 months in duration, with specific intermediate and final milestones identified at project onset. Funding up to $500,000 per project per year will be considered, inclusive of all direct and indirect expenses (Foundation policy is to limit indirect expenses to 10%). Project funding may be extended past the first year if milestones are met. Projects that require lower levels of funding are also welcome. Project cost-sharing, through which Foundation funds would be complemented using additional sources of funding to achieve project goals, is encouraged. The Foundation will not take intellectual property (IP) interest in relation to EI awards. In the event that the funded technology becomes commercially successful, the Foundation would receive a financial return (see Appendix C).

In addition to direct funding, the Crohn’s & Colitis Foundation will provide accelerator resources to provide support for funded programs. Such support will be tailored to the specific program and may include scientific review; strategic advising; patient and clinician insights; assistance in identifying research resources; facilitation of strategic partnerships (including identification of and referral to specific potential partners); assistance with clinical trial recruitment; presentation opportunities; and consideration for future Foundation funding opportunities. Accelerator support will be provided by Foundation staff, advisors from diverse backgrounds and Foundation partners.

3. Eligibility
The following types of organizations are eligible to apply for this award if the following criteria are met. Applicants not meeting the specified criteria based on the LOI submitted will not be considered for funding.

- **Company (preferred).** The majority of applicants in this category will be small for-profit biotechnology companies; nonprofit organizations meeting the criteria may also apply. This category does not include organizations whose primary mission is education, clinical care and/or basic research (e.g. universities, academic medical centers or basic research institutes). In order to qualify as a company applicant, an organization must meet the following criteria at the time of LOI submission:
  - Independent organization with a primary focus on product discovery and/or development.
  - Business plan specifying organization’s mission and projected milestones.
  - The proposed project must be consistent with the organization's business plan.
  - Funds must be available for essential company operation during the project period.
  - Full-time personnel are employed by organization.
  - Necessary infrastructure is accessible for proposed research activities.
  - Core IP for the proposed product must be assigned or licensed to the applicant.

...
• **Academic or research institution.** Projects led by investigators at universities, research institutes and medical centers may be proposed. **Academic applicants must demonstrate commitment to, and experience with, commercialization-oriented activities, and access to appropriate resources for commercialization.** Such resources may include SBIR award(s), intramural accelerator programs, industry-sponsored research, drug discovery core facilities, contract research organizations, entrepreneur-in-residence programs, etc. Basic research programs are not eligible unless described work is directly related to a product discovery/development objective. Applicants are encouraged to discuss the application with relevant institutional officials (e.g. technology transfer officer). Access to commercialization-oriented resources is preferred (e.g. SBIR award, accelerator award, industry-sponsored research, participation in drug discovery core, etc.). Preferably, at least one full-time staff member should be dedicated to the proposed project. Projects associated with invention disclosures, patent applications and/or other IP (e.g., proprietary assays) are preferred.

For both applicant categories, collaborative projects will be considered, including projects involving an academic investigator and an industry partner. Applications should identify one organization as the primary applicant. Collaborating organizations should also be identified at the time of application. There is no preference regarding applicant’s location (international applicants are welcome).

In addition, the following are required for eligibility for all EI applicants:

- Principal investigator with appropriate scientific expertise
- Demonstrated commitment to product discovery/development
- Commercialization strategy for proposed product in IBD
- Product development plan with milestones
- Defined path to obtain IP protection

### 4. Selection Criteria

**A. Product**

Project should describe a specific potential product with the potential for positive impact for IBD patients. Any research-based product concept will be considered, including but not limited to:

- **Therapeutics.** Small molecules, large molecules, gene therapies, cell therapies and nutraceuticals.
- **Devices and diagnostics.** Medical devices, imaging agents and laboratory tests.
- **Healthcare technology.** Software, services and other technology-based products.

Applicants should articulate a clear, up-to-date understanding of how the proposed product would address a specific unmet need in IBD. Substantiation of the unmet medical need (for example, based on clinical research or input from patients and clinicians) is encouraged. Unmet medical needs in IBD may include, but are not limited to: Improved and less toxic therapy; improved treatment of severe, unremitting, refractory and/or recurrent disease; therapeutics for fibrotic complications; improved detection and quantification of active disease states; improved prediction of inflammatory, fibrotic and/or penetrating disease; prediction of response to specific interventions; and improved management of post-surgical complications and recurrence. The proposed solution should be differentiated from available solutions. Applicants must demonstrate an understanding of the competitive landscape for the proposed product, and should articulate a barrier-to-entry strategy that should include, at a minimum, pursuing appropriate IP protection for funded activities.

**B. Research plan & budget**

The research plan and budget will be evaluated according to the following criteria: Are the proposed activities specifically focused on the development of the proposed product in IBD? Are these activities critically important to advance the product in the short term? The proposed plan and budget should include specific milestones that, if met, would increase the likelihood of successful development of the proposed product. At a minimum, milestones anticipated at six months and twelve months should be specified. The projected time and cost associated with each milestone must be described. Anticipated results should facilitate clear go/no-go decisions regarding the development of the proposed product. Alternative approaches, explicit success metrics and risk mitigation strategies should be included. Funded indirect expenses may not exceed 10% of funded direct expenses. Cost-sharing (supplementation of Foundation funds using additional funding sources to achieve project goals) is encouraged. The proposed R&D activities should consist of critical path activities required for near-term advancement of the proposed product opportunity.
Proposals should include preliminary evidence in support of the scientific validity and commercial potential. At all stages, validation studies and insights from patient data are encouraged. Applicants should prioritize those activities considered to be most critical for the discovery or development of the product. **Note that proposals focused on target identification or basic investigation of mechanisms of disease will not be considered under this mechanism.**

For therapeutics, the following stages of development will be considered:

- **Therapeutic target has been identified.** Proof-of-concept experiments have been performed, demonstrating that the proposed target is relevant for IBD. For example, such preliminary data may include pharmacological or genetic manipulation of the pathway in a relevant *in vitro or in vivo* model. Insights derived from human data (such as the identification of relevant biomarkers in clinical samples) are encouraged. Demonstration of a well-designed assay to screen candidates is also encouraged. At this stage, fundable activities may include optimization of screening assays (miniaturization, etc.), high-throughput screening or design of candidates through medicinal chemistry and/or protein engineering approaches.

- **Preliminary candidates have been identified.** Fundable activities at this stage may include identification of lead development candidates, drug delivery strategies, efficacy studies (e.g. multiple disease models, dose-response, and/or route of administration consistent with the intended clinical application), safety studies (e.g. *in vivo* maximum tolerated dose studies), PK-PD studies, identification of relevant biomarkers (e.g. for PD assessment), screening and/or chemistry for lead optimization, and elucidation of therapeutic candidate’s mechanism of action.

- **Lead candidate has been nominated.** Fundable activities may include additional efficacy studies in an additional species, detailed PK-PD studies, characterization of clinical biomarkers, development and validation of assays for cGMPs or clinical biomarkers, or process development for API synthesis. More advanced activities (such as IND-enabling GLP toxicology, cGMP manufacturing, IND filing, or Phase I clinical studies) may be proposed; however applicant should identify additional funding sources to supplement Foundation funds to reach such milestones.

For laboratory diagnostics, target biomarker must be identified and prior demonstration of feasibility of detection in clinical samples is required. For devices, software and imaging modalities, demonstration of feasibility (e.g. a functioning prototype) is required. Funded activities for diagnostics, devices and software may include assay development, prototyping and validation.

**C. Applicant**

Applicant organizations are expected to demonstrate the necessary capabilities, personnel and infrastructure to develop the proposed product. Applicants should have an operating plan and budget and the proposed project should be consistent with the organization’s mission. First-time entrepreneurs are encouraged to apply; however, capabilities and prior achievements in product discovery, development and commercialization will be considered. Commitment to IBD research, for example based on a track record of contribution to the field, will be considered. Organization’s general resources, including a balanced team covering general management, operations, R&D and commercial functions; fundraising to date; infrastructure; IP portfolio; contractor and vendor networks; and active collaborations with academics and industry will also be considered. Prior to funding, Foundation staff will perform due diligence.

**D. Commercialization potential**

Criteria will include the unmet medical need for the proposed product; differentiation; IP; go-to-market strategy (including clarity on regulatory pathway); likelihood of early partnerships; consideration of initial clinical indication(s) and minimum requirements to reach clinical proof-of-concept. Applicant must have assignment or license to any required IP associated with the proposed product, and preferably should have evaluated freedom to operate in advance.

**5. Application instructions & timeline**

All organizations developing research-based products for IBD are invited to contact the Foundation by submitting a Letter of Intent (LOI) form. Forms will be reviewed on a rolling basis by Foundation staff and applicants will receive a response within four weeks after submission. Applicants should indicate, at the time of LOI submission, interest in submitting a project proposal for the next cycle of review for the EI Initiative. If that does not apply, LOI submission is nevertheless encouraged if the applicant may be interested in engaging with the Crohn’s & Colitis Foundation regarding development of a product for IBD. Such applicants will be considered for future funding opportunities and additional Foundation support (including advising, clinical trial recruitment assistance and presentation opportunities). An applicant organization may submit multiple LOIs for individual projects. Selected applicants will be invited to submit a detailed full proposal for project funding. Full proposals will not be reviewed without prior submission of a LOI. Applicants will have a minimum of four weeks to prepare and submit a full proposal. Full proposal formatting guidelines and submission form will be provided. Full proposals will be
reviewed by a dedicated committee twice per year (see Appendix B). Following review, applicants selected for funding will be notified; award terms will be proposed and negotiated; Foundation staff will perform due diligence as needed (e.g. verification of contractual relationships and IP filings); and selected awardees will receive a proposed award agreement. Once contractual terms are finalized, applicant will receive a letter of funding commitment. Strict confidentiality will be maintained by Foundation for all submitted materials. Applicant may request a confidentiality agreement at any time in the application process. In some cases, a project may be identified with potential for funding, but for which additional information and/or revisions are required. In that case, applicants will be notified of requested revisions and will have the opportunity to resubmit. Depending on the extent of revisions required, the resubmission may be reviewed by Foundation staff or by full committee review. Applicants should review award terms (see Appendix C) and should indicate any potential disagreement in advance of full proposal submission. A contract template may be provided upon request.

To be considered for the upcoming cycle of review, please submit Letter of Intent by 8:00 PM EST on January 22, 2018. Applicants interested in funding in the first cycle should be prepared to submit a full proposal by March 12, 2018 if invited to do so.

Application may be accessed and must be submitted through proposalCENTRAL:

https://proposalcentral.altum.com/

Navigate to the ‘Grant Opportunities’ tab (top right) and filter by grant maker (select ‘Crohn’s & Colitis Foundation’) to find the application link for the Entrepreneurial Investing Award.
Appendix A: Letter of Intent questionnaire
All Letters of Intent must be submitted through proposalCENTRAL:

https://proposalcentral.altum.com/

Navigate to the ‘Grant Opportunities’ tab (top right) and filter by grant maker (select ‘Crohn’s & Colitis Foundation’) to find the application link for the Entrepreneurial Investing Award.

For your convenience in filling out the LOI questionnaire, questions contained in the online form are listed below.

1. Application title. (Required. Max 250 characters.)
2. Please describe how you heard about this program. (Required. Max 1000 characters.)
3. (Y/N) Would you be interested and able to submit a 5-page research proposal for the EI Award by September 5th 2017, if invited to do so? (Required)
4. (Y/N) Are you interested in additional resources the Foundation could provide, such as: scientific advising; clinical advising; recommendations regarding potential partnerships; access to research resources; patient/clinician insights; and/or presentation opportunities? (Optional).
5. Please describe the resources you are most interested in. (Optional. Max 3000 characters.)
6. (Y/N) Are you interested in setting up a confidentiality agreement for further discussion? (Optional)
7. PI Name (Prefix, *First, Middle, *Last) (Required)
8. PI Highest Degree (Required)
9. PI Primary affiliation (Required)
10. PI Additional affiliation(s) (Required)
11. PI Position/Title (Required)
12. PI Address (Required)
13. PI Email (Required)
14. PI Phone (Required)
15. Lead Organization Name (Required)
16. Lead Organization Address, City, State, Zip, Country (Required), website (optional)
17. Choose the type of organization for the prime applicant: (Required)
   For-profit small technology company (<25 employees)
   For-profit medium-sized or large company (>24 employees)
   Non-profit organization
   Academic or research institution
   Clinical organization
   Other
18. Organizational Contact Name (Required) (may be same as PI)
19. Organizational Contact Position/Title with applicant organization (Required)
20. Organizational Contact Email (Required)
21. Organizational Contact Phone (Required)

22. (Y/N) Is the lead organization an independent entity with a primary focus of product discovery and/or development? (This does not include institutions whose primary mission is education, basic research or clinical services.) (Required)

23. Companies: Describe the mission, core competencies and business model of the applicant organization. Academic investigators: Describe the research and product development goals of the research group. (Max 3000 characters.) (Required)

24. (Y/N) Does the organization have full-time employees? (Required)

25. List key project personnel. Indicate role in the organization, percent time commitment at the time of application, anticipated percent time commitment during proposed project term (if applicable), date recruited to team and relevant experience. Describe experience in IBD. Company applicants may include management staff. Advisors may be included. Include weblink profile (LinkedIn or other) if available. (Max 6000 characters.) (Required)

26. (Y/N) Does the organization have operating funds for essential company activities for the next 12 months? (Required)

27. Briefly describe applicant’s relevant R&D infrastructure, including laboratories, and/or information technology systems. Key collaborators or contractors may also be identified here. For academic applicants, describe access to commercialization-oriented infrastructure. (Max 6000 characters.) (Required)

28. Describe related funding and resources secured to date. (Optional. Max 3000 characters.)

29. If the company has additional marketed or investigational products, in addition to the product described, so describe. If any such products are currently in clinical testing, so describe. (Optional. Max 3000 characters.)

30. (Y/N) Are you proposing the discovery and/or development of a specific product intended to cure IBD or improve the quality of life of adults and children affected by IBD? (Required).

31. Project description. Briefly describe the proposed product for IBD. (This description is for informational purposes only; you may revise the project proposal at a later time.) Include the following information:

- The problem being addressed and relevance to specific unmet needs in IBD.
- The specific product opportunity and how it would address the problem.
- Description of the underlying technology and preliminary data.
- Design of proposed studies with timeline, specific objectives and expected outcome (if applicable).
- Anticipated milestones with metrics for success. How would milestones increase probability of successful product development?
- Approximate funds required to reach indicated milestones.

(Required. Max 6000 characters.)

32. (Y/N) Does the applicant have partnerships or collaborations, especially any related to the proposed product? (Required)

33. If Yes: Describe. (Optional. Max 3000 characters.)

34. Choose the product category: (Required).

i. Small molecule
ii. Large molecule
iii. Cell therapy (including microbes)
iv. Vaccine
v. Gene therapy
vi. Laboratory diagnostic
vii. Imaging modality
viii. Other medical device
ix. Software
x. Service
xi. Combination product
xii. Other

If the proposed product is a therapeutic, answer questions 35-53 (Optional).

35. (Yes / No / Not applicable) Has a proprietary molecule been generated?
36. (Yes / No / Not applicable) Has a proprietary molecule library been generated or screened?
37. If yes, what is the size of the library and how is it being accessed? (Max 1000 characters)
38. (Yes / No / Not applicable) Has the therapeutic target been validated in IBD?
39. If yes, how? (Max 1000 characters)
40. (Yes / No / Not applicable) Has high-throughput screening been initiated?
41. If Yes describe; if not, when will screening be performed? (Max 1000 characters)
42. (Yes / No / Not applicable) Has a biochemical or phenotypic screening assay been developed?
43. If yes, what is the throughput of such assay(s)? (Max 1000 characters)
44. (Yes / No / Not applicable) Has the therapeutic target been validated in IBD?
45. If yes, how? (Max 1000 characters)
46. (Yes / No / Not applicable) Has an appropriate formulation been developed?
47. (Yes / No / Not applicable) Have experiments been performed to determine absorption, distribution, metabolism and/or safety?
48. (Yes / No / Not applicable) Has any GLP toxicology or GMP process development been initiated?
49. (Yes / No / Not applicable) Was there a manufacturing process in place?
50. (Yes / No / Not applicable) Could the existing manufacturing process be adapted for production of clinical material?

51. (Yes / No / Not applicable) If the proposed product is a device, diagnostic or piece of software, has a functional prototype been generated? (Optional)
52. Describe, at a high level, the proposed commercialization path for the proposed product, for example, the intended regulatory pathway and how the product would eventually be sold. Explain how the development of the proposed product fits into the overall mission and business plan for the organization. If a commercialization strategy has not been generated or is not applicable, so indicate. (Required. Max 3000 characters)
53. (Yes / No / Not applicable) Are invention disclosures, patent applications, granted patents or other IP associated with the proposed product? (Required)
54. (Yes / No / Not applicable) Are there invention disclosures, patent applications, granted patents or other IP associated with the proposed product? (Required)
55. If Yes: Describe. (Optional. Max 6000 characters.)
56. (Y/N) Does the applicant believe that freedom to operate exists for the proposed product? (Optional.)
57. If Yes: Describe how this was determined. If No: Explain how this will be addressed. (Optional. Max 3000 characters.)
58. Enter any peer-reviewed publications associated with the proposed project. List publications in chronological order. Include only publications directly related to applicant’s research program or IP. Limit your entries to 10 total publications. (Optional.)
59. (Y/N) Has the program benefited from accelerator resources, such as drug discovery or device prototyping accelerators? (Required)
60. If yes, so describe. (Optional. Max 2000 characters.)
61. Attach an investor-oriented slide presentation (max 20 slides) and/or 1-page executive summary. (Optional.)
Appendix B: Review process & policies
Stringent expert peer review is a critical component of the Foundation’s research initiatives. For EI Awards, a multidisciplinary review process will be applied to critically evaluate scientific and commercial merit of proposed projects. Letters of Intent (see Appendix A) will be evaluated by Foundation staff with experience in biomedical product discovery/development to determine eligibility and fit with the EI program. Eligible applicants will be invited to submit a full proposal. Full proposals will be evaluated by a multidisciplinary committee according to explicit review criteria to be provided to applicant when the full proposal is requested. The review committee will comprise: academic investigators with expertise in IBD research (laboratory and clinical); industry scientists with expertise in product discovery and development; professionals with experience in biomedical entrepreneurship, venture financing, venture formation, business development, technology transfer and IP; IBD patients; and Foundation staff. Additional reviewers may be included on an ad hoc basis when additional specialized expertise is required for review.

Full proposals will be evaluated under strict confidentiality in accordance with a confidential disclosure agreement to be executed by applicant and Foundation officials. In order to serve on the EI Award review committee for a given cycle, committee members must meet the following criteria:

Must lack a significant interest (financial or otherwise) in any proposal under review in that cycle.
Must have disclosed any direct or indirect links to industry, such as pharmaceutical, medical device, health insurance, and healthcare related companies, that have the potential to bias or appear to cause bias in the review process.
Must have commitment to maintain strict confidentiality.
Must not be a board director or corporate officer for an entity developing and/or selling IBD-related products/services.
Must have disclosed any actual or potential conflicts.

In addition, Committee members will recuse themselves from the review of a specific proposal if:

Member has a significant financial interest in the outcome of that proposal.
Member has a significant financial interest in an organization that is in direct competition with the applicant entity.
Appendix C: Award terms

The following is an outline of certain terms and conditions that, together with additional customary terms, will be required to be included in a final award agreement. The Crohn’s & Colitis Foundation will not take equity interest nor IP ownership in relation to the Awards.

1. Funding to be paid by CROHN’S & COLITIS FOUNDATION to applicant on a milestone basis during the period of the funded research program.

2. Return payment to CROHN’S & COLITIS FOUNDATION on commercialization of a product from funded invention/technology or any improvement thereto, corresponding to a multiple of CROHN’S & COLITIS FOUNDATION funding (such multiple will be determined upon agreement between applicant and CROHN’S & COLITIS FOUNDATION to account for risk and award amount).

3. Partial return payment to CROHN’S & COLITIS FOUNDATION on early exit event(s), e.g. option/out license and/or change of control transaction, with any remainder to be paid at commercialization.

4. Upon cessation by Applicant of active development in IBD field for business reasons (i.e., not for scientific failure) prior to commercialization or full satisfaction of point 3 above, Applicant and CROHN’S & COLITIS FOUNDATION will have agreed to one of the following: repayment to CROHN’S & COLITIS FOUNDATION with interest at a compounded rate the funding provided by CROHN’S & COLITIS FOUNDATION; substitution of a different invention/technology for development in the IBD field which will be subject to above CROHN’S & COLITIS FOUNDATION repayment terms; or outlicense funded invention/technology to CROHN’S & COLITIS FOUNDATION on mutually agreeable terms.

5. Twice yearly reports for 2 years after initiation of funding and annual reports from end of research program until full satisfaction of 2. Reports must be satisfactory to CROHN’S & COLITIS FOUNDATION and should include description of research and IP activities.

Please indicate any disagreement with any of the above in making your funding proposal.
Appendix D: Frequently asked questions

1. What is the Entrepreneurial Investing Initiative?

The Entrepreneurial Investment (EI) Initiative is a funding mechanism intended to accelerate the discovery and development of novel research-based products with the potential to alleviate suffering caused by Inflammatory Bowel Disease (IBD).

2. What types of potential products may receive funding?

Any research-based product with the potential to address an unmet need of IBD patients will be considered.

3. Who is eligible for this award?

We anticipate that the majority of recipients will be companies with a primary focus on product discovery and/or development. Companies should have independent operations, appropriate capabilities and full-time staff. Investigators at academic institutions are also eligible if they can access appropriate resources for product development.

4. How can I access program information and application forms?

Application may be accessed and must be submitted through proposalCENTRAL: https://proposalcentral.altum.com/

Navigate to the ‘Grant Opportunities’ tab (top right) and filter by grant maker (select ‘Crohn’s & Colitis Foundation’) to find the application link for the Entrepreneurial Investing Award.

5. Is there a deadline?

No. LOIs can be submitted at any time and will be reviewed on a rolling basis. However, proposals will be reviewed twice per year; in order to be considered for the upcoming review cycle, LOIs should be submitted by the corresponding deadline.

6. How will Letters of Intent be reviewed?

All organizations developing research-based products for IBD are invited to contact the Foundation by submitting a Letter of Intent (LOI) form. Forms will be reviewed on a rolling basis by Foundation staff and applicants will receive a response within 4 weeks. Applicants should indicate, at the time of LOI submission, interest in submitting a project proposal for the next cycle of review for the EI Award.

7. Should I submit a Letter of Intent (LOI) even if I am not interested in or eligible for this award?

Yes! Even if you do not intend to apply for this award, we still want to hear from you. LOI submission is encouraged if you are interested in engaging with the Crohn’s & Colitis Foundation regarding development of a product for IBD. LOIs will be considered for future funding opportunities and additional Foundation resources (including advising, clinical trial recruitment assistance and presentation opportunities).

8. How will full proposals be reviewed?

Full proposals will be reviewed by a multidisciplinary committee comprised of industry scientists; academic scientists; clinical experts; entrepreneurs; business development and venture professionals; and IBD patients.

9. Can I submit a full proposal if I have not previously submitted a Letter of Intent?

No.

10. Will the Crohn’s & Colitis Foundation treat submitted materials in a confidential manner?

Yes. All submitted materials will be treated in a confidential manner and will be used only for the purposes for application review. Full proposals will be treated as confidential and a confidentiality agreement will be provided in advance of submission. If the applicant would like the LOI to be treated as confidential, a confidentiality agreement may be requested in advance of LOI submission.
11. Will the Crohn’s & Colitis Foundation offer additional resources for awardees in addition to funding?
Yes. Accelerator resources will be provided to support ventures, including scientific and strategic advising, according to the needs of each funded program.

12. Is the EI funding project-based?
Yes, funding will be project-based funding with specific milestones established in advance.

13. Will the Crohn’s & Colitis Foundation ask for equity in funded companies?
No.

14. Will awards be associated with a financial commitment?
Yes. If the funded technology is successfully commercialized, payment would be due back to the Foundation.

15. What should be the estimated duration of funded programs?
Approximately one year.

16. Will funded programs be eligible for extended funding beyond the first year?
Yes, especially if milestones are achieved.

17. Are there any limitations as to the type of technology that might be funded?
No, so long as there is clear potential for benefit for IBD patients.

18. Are commercial-stage or public companies eligible for the EI Award?
Yes, any company meeting the eligibility criteria is eligible to apply.

19. Can applicants be located outside the US?
Yes.
Appendix E: Full Proposal Format
Applicants will be asked to submit the following documents in PDF format for full proposal consideration. Text documents should use 11-pt or larger Arial font and not less than ½ inch margins.

- Research plan (up to 5 pages)
- Commercialization plan & resources (up to 1 page)
- Key personnel and R&D resources (up to 1 page)
- Milestones & timeline (Gantt chart or similar) (up to 1 page). Activities outside the scope of the funded proposal, but related to the proposed product, may be included (e.g., using a different color).
- Milestone-driven budget summary table (up to 1 page). When Foundation funding would be supplemented by additional funds, such funding may be indicated in a separate column. Overhead items and development activities occurring in parallel with funded activities may also be indicated
- Lay-accessible abstract
- Scientific abstract
- Slide presentation (up to 20 slides)
- Resumes/CVs for key personnel (optional)
- Letters of support (optional)