

***Prostate Cancer Foundation and Bayer Announce:
2023 Bayer-PCF Darolutamide Challenge Awards
For Clinical Investigations on Novel Uses of Darolutamide in Prostate Cancer***
REQUEST FOR APPLICATIONS

The Prostate Cancer Foundation (PCF) and Bayer are pleased to announce a Request for Team Science Applications for Bayer-PCF Challenge Awards for novel investigator-initiated clinical investigations with correlative research for darolutamide in prostate cancer. These awards will be funded depending on the level of innovation in applications received. PCF and Bayer seek high-risk, currently unfunded projects from academic institutions in the United States (U.S. only).

Bayer-PCF Challenge Awards:

- Composed of a team of at least three (3) investigators from non-profit academic research centers in the U.S., including one young investigator (see PCF Challenge Award Team requirements below).
- Support novel clinical investigations with correlative research for darolutamide in prostate cancer, over a duration of two years.
- Provide up to a total of \$1 million per team. Approximately \$3 million will be designated for this award mechanism.
- Cover only direct research costs and travel to the Annual PCF Scientific Retreat.
- IRB submission and preferably approval is desired at time of application.

Research Proposals:

- This RFP seeks proposals for novel investigator-initiated clinical investigations with correlative research for darolutamide in prostate cancer. A novel clinical trial must be part of the proposed research project.
- Investigations may be in the following topic areas:
 - Novel clinical spaces for darolutamide in prostate cancer.
 - New combination treatment approaches with established or experimental drugs that capitalize on different mechanisms of action for eradication of prostate cancer.
- Studies must include correlative research that aims to help better define biomarkers or other understandings that will improve the clinical use of darolutamide in patients with prostate cancer, to increase efficacy and/or quality of life.
- All studies should include comprehensive statistical plans for clinical trial enrollment and power calculations.
- All studies must include plans for enrolling diverse participant populations with appropriate representation of ethnic and racial minority groups.
- Applications for trials testing combinations with non-Bayer assets may seek clinical trial support from other companies or organizations.

The Bayer-PCF Challenge Award Team:

- Should be composed of at least 3 investigators capable of providing unique scientific expertise to the solution of this significant problem in prostate cancer research.
- May be assembled from one institution, or several institutions, located in the U.S.
- Must embed at least one young investigator as an integral contributor to the team. The young investigator may hold the title of Postdoctoral Fellow, Instructor, Research Associate, Assistant Professor, or equivalent and should be within six-years following completion of a professional degree (MD, DO, PhD, MD-PhD, DSc, ScD, DDM, DDS, DMD, MBBS, or equivalent) or subsequent mentored academic or clinical training program. He or she should not have been granted commitments for more than \$300,000 in direct research funding from all sources including institutional funds at the time of this application.
- Applicants who are under-represented in biomedical research are highly encouraged to apply.

Bayer-PCF Challenge Award Application Guidelines

Eligibility:

Investigators representing non-profit academic research centers in the U.S. are eligible to apply for PCF Challenge Awards. Investigators from for-profit companies and government-sponsored institutions, with the exception of the VA, are ineligible.

Application Form: To be completed online by the Principal Investigator under their name at <https://pcf.smartsimple.com>. Names and contact information for all team members listed in the Research Proposal must be added to the online application. Collaborators who are not team members but will collaborate on the project, wrote letters of recommendation, or otherwise contributed to the application must also be listed on the online application.

Research Proposal: The following sections are required for application to the Bayer-PCF Challenge Award. With the exception of the Abstract (fill-in field), the Research Proposal and all supporting documents listed below should be uploaded as separate PDF files. Please note that item 7 is optional.

1. **A scientific abstract** concisely describing the background, rationale, specific aims, experimental approach and anticipated outcomes and impact of the project is required (fill-in form field).
 2. **Statement of Originality (1-page limit):** This statement delineates why the work is first-in-field, original, and currently unfunded. PCF and Bayer seek new and never-before tested ideas, not derivatives of ongoing investigations or incremental research.
 3. **Research Proposal:** The narrative text and any preliminary data supporting a 2-year research proposal, limited to **10 pages**, plus a list of references cited (references not to be counted toward the 10-page limit). For investigations that involve clinical trials, inclusion of a statistician and a clear statistical plan to justify the size of the study population is mandatory.
 4. **NIH Biosketch:** Please submit a NIH Biographical Sketch for each investigator (5-page max), including a list of relevant publications and currently funded research projects (include award or grant type, project title, funding source, amount, and beginning and end dates of funding). NIH Biosketches for all investigators on the team award proposal should be combined and uploaded as a single PDF document.
 5. **Budget page(s):** Please include an annual budget breakout grid and budget justification for the proposal. This award mechanism will cover only direct costs (no overhead). The budget can be prepared using NIH Budget forms like PHS 398; however, use of these forms is not mandatory. All PCF Challenge Award PIs and Co-PIs must use funds from the PCF Challenge Award to cover travel and registration expenses to attend the Annual PCF Scientific Retreat. Attendance by at least one member of the team each year is required for the duration of the award. The Retreat will be held in Carlsbad, CA.
 6. **Clinical trial protocol and a timeline for activation of the clinical investigation.**
 7. **Supplemental Information (Optional):** Supplemental information in support of the application such as previous highly relevant publications or accepted manuscripts, letters of collaboration and letters of support can be uploaded as a single PDF document.
- **If applicable, at the time of the award, an IRB-approved protocol ready for activation is preferred for all human-related studies, including specimen acquisition. In addition, documentation of the availability of the experimental agent to be studied is required.**

Funding decisions will be made following peer and programmatic review. Representatives from Bayer will be included in the review processes and have access to applications. Reporting results and the budget process will be discussed at the time of announcement of the awards.

Visit <https://pcf.smartsimple.com> on or after **Friday, March 31, 2023**, to complete the online full application form and attach the PDFs.

The deadline for full application submissions is **Monday, June 5, 2023, at 3:00 p.m., Eastern Daylight Time (EDT)**

***** In fairness to all there will be no exceptions to this deadline. *****

Please direct questions to applications@pcf.org.

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