

SANOFI GENZYME
Medical Affairs
Request for Proposals

Date: January 12, 2017		
Disease State: Oncology		
Therapeutic Area: Oncology		
Area of Interest: Prostate Cancer		
Geographic Scope: US		
Internal Requestor Information:		
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Due Date: March 7, 2017		
Submission Portal: https://sgrants.envisionpharma.com/vt_sgrants/		

Health Care Gap

In the United States, approximately 181,000 new cases of prostate cancer are diagnosed annually¹. Prostate cancer is the most common cancer in men, and accounts for ~11% of all new cancer cases in US and ~27% of new cancer cases in men.¹ It is the second leading cause of cancer death in American men. In 2013, there were an estimated 2,850,000 men living with prostate cancer in the US.² The death rate from prostate cancer among African Americans is over twice as high as that among non-Hispanic white men.²

Approximately 10-20% of newly diagnosed prostate cancer cases involve locally advanced disease and recent patterns suggest that an increasing percentage of men will present with high volume metastatic disease that will be hormone/castration-sensitive.¹

Moreover, for castration resistant prostate cancer, multiple new treatments have been approved by the FDA since 2004.

ASCO, AUA, and other professional societies offer guidelines for the care of prostate cancer patients. These guidelines recommend a multimodality approach to include chemotherapy, anti-androgen therapy, radiotherapy, immunotherapy, and androgen receptor (AR)-targeted therapy, as well as clinical trials.³

Yet prostate cancer remains difficult to treat due to its heterogeneity and spectrum of aggressiveness⁴. Thus, tumor heterogeneity affects the clinician's ability to predict response to systemic therapy. It is believed that 30-40% of patients with prostate cancer do not receive optimal care.⁵ Wide variation in treatment approaches observed in practice suggests an unmet need to improve the individualized approach towards patient care.⁴ Recent data re: AR-targeted agents, chemotherapy and effective sequencing of these and other therapies may be factors to consider in optimizing care and establishing standard treatment paradigms.⁶. Thus, selecting the

right therapy for the right patient at the right time and providing the most cost-effective treatment are unmet needs in this disease

As an increasing number of advanced prostate cancer patients live longer, there is a growing need to identify and train more qualified clinicians, and to develop centers of excellence with the capability and expertise to treat patients with all therapeutic modalities.

Providing treatment on an outpatient basis may be advantageous for the optimal care of advanced prostate cancer patients. From a cost perspective, across a variety of payer programs, office-based outpatient delivery of various therapies may result in cost savings over the hospital-based inpatient and outpatient settings.¹⁴⁻¹⁶ From a patient perspective, the advantages of office-based treatment potentially include optimal continuity of care and a reduced amount of time spent in the hospital setting.

Medical oncologists often provide office-based treatment across all available modalities. On the other hand, in spite of the potential cost savings and patient benefits, the adoption by urologists of all of these treatment modalities on an in-office basis has been more limited.¹⁷ This may be due to gaps in urology training curricula, but also to limited knowledge of the requirements for infrastructure, nursing capability, and administration.

SANOI GENZYME is seeking proposals to close this independently defined healthcare gap to improve clinician (particularly urologist) knowledge of how to provide prostate cancer therapies that improve overall survival and quality of life for patients with advanced disease through independent medical education designed according to well-referenced learner preferences.

Single supported and multi-supported proposals will be considered *with a maximum request not to exceed \$150,000.*

Please note that proposals are expected to include an analysis of the barriers and root causes for this gap and how the educational intervention would address this gap.

Proposal should include the following information:

- **Needs Assessment/Gaps/Barriers:** Include a comprehensive needs assessment that is well referenced and demonstrates an understanding of the specific gaps and barriers of the target audiences (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>. Accreditation Criteria. Accessed 8 April 2016).⁸ **The needs assessment must be independently developed and validated by the accredited provider**
- **Target Audience and Audience Generation:** Proposal should describe the target audience(s) and provide a rationale for how and why this target audience is important to closing the identified healthcare gap. In addition, please describe methods for reaching the target audience(s) including description of and rationale for recruitment and placement strategies to maximize participation according to need. Any unique recruitment efforts specific to the target audience should be highlighted.

- **Learning Objectives and Content Accuracy:** Provide clearly defined and measurable learning objectives framed as expected practice improvements in relation to the identified gaps and barriers. Include an overview of program content and explanation of criteria that will guide content selection, considering level of evidence and other variables. SANOFI GENZYME is committed to the highest standards in ensuring patient safety; the applicant should describe methods to ensure complete, accurate, evidence-based review of key safety data for any therapeutic entities discussed in the activity. Explain how content will be updated if necessary throughout the program period, and how accuracy will be ensured.
- **Educational Methods:** The ACCME calls for educational methods that are clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap. Your proposal should demonstrate an understanding of instructional design issues as they relate to the gaps in the knowledge, competence, or performance of the targeted audience. Education methods and design should be based on current literature in continuing education best practice and consistent with ACCME accreditation elements (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>. Accreditation Criteria. Accessed 8 April 2016).⁸ For example, systematic reviews have suggested that the most effective continuing education is clearly linked to clinical practice, uses methods including interaction, reflection, strategies that ensure reinforcement through use of multiple educational interventions, and more.^{9,10,11,12} Preference will be given to applications that utilize methods that have been shown to result in practice improvements, and/or with data on the effectiveness of other programs of the same type. ACCME criteria recognize that barriers may be related to systems, lack of resources, or tools etc. and these may be included if relevant in your discussion of the gap and the educational methods you propose. In addition, the educational preferences of the target audience(s) may be considered to maximize attendance/participation and lead to practice improvements.
- **Faculty Recruitment and Development:** Provide Information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications. Explain any methods that will be used to ensure that faculty are fully trained in the program expectations and any skills that may be needed to ensure effective delivery of intended education.
- **Program Evaluation and Outcomes:** Provide a description of the approach to evaluate the reach and quality of program delivery; methods for monitoring individual activities and for ensuring ongoing quality improvements (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>. Accreditation Criteria. Accessed 8 April 2016).⁸ Describe methods that will be used to determine the extent to which the activity has served to close the identified healthcare gap. (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>. Accreditation Criteria. Accessed 8 April 2016),⁸ and the qualifications of those involved in the design and analysis of the outcomes. Preference will be given to programs with Objectives and Outcomes Plans of Moore level 4-6.¹³

- **Budget:** Include a detailed budget with rationale including breakdown of costs, clear explanation of the units, and calculations of:
 - Content cost per activity
 - Out-of-pocket cost per activity
 - Management cost per activity

- **Accreditation:** Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Commercial Support™. ***If you are a non-accredited provider, the accredited provider must be involved from the concept origin, fully knowledgeable of the grant submission and documentation should be provided on the website grant application section entitled, “Other Information”.***

- **Resolution of Conflict:** The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, with particular emphasis on ACCME criteria (<http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>. Accreditation Criteria. Accessed 8 April 2016).⁸

- **Communication and Publication Plan:** Provide a description of how the provider will keep the supporter informed of progress. Include description of how the results of this educational intervention will be presented, published or disseminated.

1. American Cancer Society. Key Statistics for Prostate Cancer. <http://www.cancer.org>. Accessed on October 30, 2016.
2. <http://seer.cancer.gov/statfacts/html/prost.html>. Accessed on October 30, 2016.
3. Prostate Cancer. V1 .2013. National Comprehensive Cancer Network. http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf. Accessed Feb 6, 2014.
4. Joniau et al. Ther Adv Urol. 2013 October; 5(5): 233-244.
5. Heidenreich A., et al. (2011) EAU guidelines on prostate cancer. Part 1. Eur Uro/59:61-71.
6. Sweeney et al. CHAARTED Trial. NEJM 2015
7. James et al. STAMPEDE Trial. ASCO 2015
8. <http://www.accme.org/requirements/accreditation-requirements-cme-providers/accreditation-criteria>. Accreditation Criteria. Accessed 8 April 2016).
9. Davis, D.B., B.E., Fox, R., The Continuing Professional Development of Physicians - From Research to Practice, ed. R.t. Practice. 2003, Chicago: AMA.
10. Davis, D., et al., Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes? JAMA, 1999. 282(9): p. 867-74.
11. AHRQ, Effectiveness in Continuing Medical Education, in Evidence Report No. 1492007.
12. Armstrong, G., et al., Designing education to improve care. Jt Comm J Qual Patient Saf, 2012. 38(1): p. 5-14.
13. Moore, D.E., Jr., J.S. Green, and H.A. Gallis, Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. J Contin Educ Health Prof, 2009. 29(1): p. 1-15.
14. Fitch K, Pyenson B. Site of service cost differences for Medicare patients receiving chemotherapy. Milliman Client Report. Oct 19, 2011. Access at

<http://us.milliman.com/insight/health/Site-of-Service-Cost-Differences-for-Medicare-Patients-Receiving-Chemotherapy/>

15. Fitch K, Iwasaki K, Pyenson B. Comparing episode of cancer care costs in different settings: An actuarial analysis of patients receiving chemotherapy. Milliman Client Report August 29, 2013. <http://us.milliman.com/uploadedFiles/insight/2013/comparing-episode-cancer-care.pdf>
16. Hayes J, Hoverman JR, Brow ME et al. Cost differential by site of service for cancer patients receiving chemotherapy. *Am J Manag Care*. 2015; 21: e189-e196.
17. Engel-Nitz NM, Alemayehu B, Parry D, Nathan F. Differences in treatment patterns among patients with castration-resistant prostate cancer treated by oncologists versus urologists in a US managed care population. *Cancer Management and Research* 2011; 3: 233–245.