Daiichi-Sankyo

Requests for Proposal

Calls for Continuous Grant Submissions

Fiscal Year (FY) 2023:

April 1, 2023 - March 31, 2024

Issuance Date: January 25, 2023

Daiichi Sankyo, Inc.

Medical Proficiency Acceleration Center:

Office of Grants & Education, OGE-CME@DSI.com

Grant Submission Site: https://daiichisankyo.us/corporate-giving-and-support

Information for Submissions:

Material in the below "Contents" section is interactive with linkable, and directive clicks

Daiichi Sankyo believes education is a source to accelerating best, personalized evidence into clinical practice for the best interest of patient care. Our commitment is to make grant funding available for independent, fair, balanced, and scientifically accurate medical education initiatives that receive no influence from our organization in submission, design, or implementation. Grant conduct is required to comply with all expected regulatory requirements. At times, Daiichi Sankyo accepts grant submissions that are in response to a Call for Continuous Grant Submissions or time-limited Request(s) for Proposals (RFPs). When published, these Calls and/or RFPs will provide details regarding externally referenced educational, clinical, practical, and/or research gaps in specific therapeutic focus areas. We invite eligible organizations to log into the grant portal for information on currently available Calls and/or RFPs throughout the year.

Gaps have been identified through a review of publicly available literature (which are resourced in separate tables), as well as internal needs assessments, internal Medical Affairs fair/balanced insights, and an evaluation of outcomes from prior independent medical education. Gaps have been allocated by recommended outcomes goals.

As of January 25, 2023, this currently is the only Daiichi Sankyo-issued Call for Continuous Grant Submissions or time-limited RFPs for Fiscal Year 2023. Daiichi Sankyo may publish revisions or additional calls and/or RFPs as the year progresses.

Activity	Due Date/Time
Packet publication and dissemination	January 25, 2023
Call for Continuous Grant Submissions: Full grant submissions provided to **https://daiichisankyo.us/corporate-giving-and-support**	Submissions for FY2023 may begin immediately upon the dissemination of this packet. We aim to make decisions within 60 days of submission. Please note decisions for FY2023 grants will not start until April 1, 2023.
Time-limited RFPs:	Currently not applicable in this issuance
Preferred start dates for education	**Call for Continuous Grant Submissions:** Continuously throughout FY2023, please check each table for specific date ranges
Preferred timing of initial **and/or** preliminary outcomes of awarded programs	Daiichi Sankyo encourages the submission of preliminary outcomes in the following manner: • **Independent Satellite Symposia**: First basic report of preliminary metrics within 24-72 hours after symposium • **All other education formats**: Preliminary report updates within 30 days after initial educational activity

Independent Medical Education Symposia at Congresses: It is important to note that Daiichi Sankyo publishes a list of U.S. congresses where we have IME symposia support interests, and outside-U.S. congresses where we have secured IME symposia slots. These lists are typically published twice per year (Summer and Winter) and provided on the Daiichi Sankyo grant submission portal. While the content provided in this packet could be useful for IME symposia submissions, this packet is not used for the request of IME symposia submissions.

Call for Continuous Grant Submissions

- **HER2 Tumors**
- **TROP2 Tumor**
- **HER3 Tumors**
- **AML**
- **B7-H3 Tumors**

Human Epidermal Growth Factor Receptor 2 (HER2) Tumors

Relevant clinical learners across all areas identified below: U.S. Oncologist**,** Community & Academic Pathologist**,** Oncology NP/PA**,** Oncology Nurse, Nurse Navigators**,** Clinical & Board-Certified Oncology Pharmacist

■ **Improved awareness and knowledge** ■ **Improved confidence in science; skills-based competence** ■ **Improved/elevated practice**

HER2 metastatic Breast Cancer (BC)	**Funding:** April 2023 – March 2024	■ Burden of disease, prevalence, and unmet need of HER2 and HER2-Low ■ Testing and interpretation of *ERBB2*(HER2) expression in mBCs ■ Identification of patients who may benefit from HER2-directed therapy based on HER2 IHC results ■ ■Treatment options, sequencing, and guideline recommended care ■ Monitoring, including early identification, and management strategies for more common and serious treatment related adverse events (AEs), including but not limited to those that impact Quality of Life
HER2 advanced gastric cancer (aGC) and gastro-esophageal cancers (GEJ)	**Funding:** April 2023 – March 2024	■ Burden of disease, prevalence, and unmet need in earlier line settings ■ Combination strategies for patients with HER2+ disease in earlier line settings ■ Testing and interpretation of erbB2 (HER2) expression ■ Monitoring, including early identification, and management strategies for more common and serious treatment related AEs, including but not limited to those that impact Quality of Life ■ And therefore, treatment options for aGC and sequencing
HER2 Non-Small Cell Lung Cancer (NSCLC)	**Funding:** April 2023 – March 2024	■ Differentiation of amplification, overexpression, and mutations for the *ERBB2* HER2 gene, and the appropriate testing modalities ■ Testing modalities including broad panel genomic testing for driver mutations, including *ERBB2* (HER2) activating mutations for advanced disease ■ Clinical trial data in key subpopulations with unmet needs, including NSCLC patients with brain metastases ■ Current and emerging clinical trial data in HER2 mutant and HER2 overexpressing landscape ■ Appropriate and current dosing regimens of HER2-directed mNSCLC agents, including those for HER2 mutations, and the management of associate adverse events ■ Monitoring, including early identification, risk factors for ILD, and management strategies for more common and serious treatment related AEs

Specified areas of needed improvement*. Please note that some prior independent educational programs, while effective, have inaccurately reported the most current published data.* ***References for the gaps identified above can be found in the appendix of this document***

Trophoblast Cell Surface Antigen 2 (TROP2) Tumors

Relevant clinical learners across all areas identified below: U.S. Community & Academic Oncologist, Community & Academic Pathologist, Community & Academic Pulmonologists (for NSCLC particularly), Oncology NP/PA, Oncology Nurse, Clinical & Board-Certified Oncology Pharmacist

■ **Improved awareness and knowledge** ■ **Improved confidence in science; skills-based competence** ■ **Improved/elevated practice**

TROP2 Breast Cancer (BC)	**Funding:** April 2023 – March 2024	■ Biology of TROP2, actionability as an ADC target, and mechanism of action of TROP2 directed therapies ■ Prevalence of TROP2 in BC, burden of disease, and the unmet need in HR+/HER2-negative breast cancers and TNBC ■ Current and emerging evidence and awareness of on-going clinical trials in HR+/HER2-negative breast cancers and TNBC ■ Mechanism of action and biology across TROP2 ADCs ■ BC TROP2 treatment options, sequencing, and emerging therapies ■ Monitoring, including early identification, and management strategies including prophylaxis, for more common and serious treatment related AEs including those that impact Quality of Life
TROP2 Non-Small Cell Lung Cancer (NSCLC)	**Funding:** April 2023 – March 2024	***Through mid-2023: Improve knowledge and competence; From mid-2023 onward: Improve confidence*** ■ ■ Biology of TROP2, prevalence of TROP2 in NSCLC, burden of disease and mechanism of action of TROP2 directed therapies ■ ■ Unmet needs in NSCLC patients with and without actionable genomic alterations ■ ■ Current and emerging evidence and awareness of ongoing clinical trials, including those utilizing TROP2-directed agents, in aNSCLC ■ ■ Combination strategies with TROP2 ADCs from early to late care ■ ■ Role of TROP2 as a therapeutic target in NSCLC ■ ■ Monitoring, including early identification, and management strategies including prophylaxis, for more common and serious treatment related AEs including those that impact Quality of Life

Specified areas of needed improvement. *Please note that some prior independent educational programs, while effective, have inaccurately reported the most current published data.* ***References for the gaps identified above can be found in the appendix of this document***

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Human Epidermal Growth Factor Receptor 3 (HER3) Positive Tumors

Relevant clinical learners across all areas identified below: U.S. Community & Academic Oncologist, Community & Academic Pathologist, Community & Academic Pulmonologists (for NSCLC particularly), Oncology NP/PA, Oncology Nurse, Clinical & Board-Certified Oncology Pharmacist

Improved awareness and knowledge **Improved confidence in science; skills-based competence** **Improved/elevated practice**

HER3 Breast Cancer (BC)	**Funding:** April 2023 – March 2024	Biology of HER3 and current evidence and awareness of on-going clinical trials Current and emerging treatment options for treatment of HR+/HER2+, TNBC, HR+/HER2-low and HER2+ BCs Monitoring and management strategies for treatment related AEs including commonly occurring AEs
HER3 Non-Small Cell Lung Cancer (NSCLC)	**Funding:** April 2023 – March 2024	Biology of HER3; incidence of HER3 overexpression in primary NSCLC tumors and upregulation of HER3 expression in EGFR TKI-resistant NSCLC cells Emerging evidence on biomarker agnostic alterations, and selection of appropriate therapies, including HER3 directed agents Unmet need after progression on multiple lines of prior systemic therapy in patients with advanced NSCLC with EGFR-activating alterations Current evidence and awareness of on-going clinical trials in the post- tyrosine kinase inhibitor (TKI), post- platinum-based chemotherapy (PBC) EGFR-mutant NSCLC Monitoring and management strategies for treatment related AEs including commonly occurring AEs

Specified areas of needed improvement. *Please note that some prior independent educational programs, while effective, have inaccurately reported the most current published data.* ***References for the gaps identified above can be found in the appendix of this document***

Hematologic malignancies and Emerging Targets

Preference may be given to effective, but cost-sensitive education and/or education planning for multi-support.

Relevant clinical learners for all areas identified below: U.S. Community & Academic Oncologists, Hematologists, and Hematologist-Oncologists**,** Community & Academic Hemato-Pathologist**,** Community & Academic Urologic Oncologist (for B7-H3 particularly), Oncology NP/PA**,** Oncology Nurse, Nurse Navigators**,** Clinical & Board-Certified Oncology Pharmacist

Improved awareness and knowledge **Improved confidence in science; skills-based competence** **Improved/elevated practice**

Acute Myeloid Leukemia (AML)	**Funding:** April 2023 – March 2024	Molecular testing, interpretation of the results and measuring minimal residual disease in the management of FLT3 mutated AML Unmet need for patients with newly diagnosed FLT3-ITD positive AML Monitoring, including early identification, and management strategies for more common and serious treatment related AEs The safe incorporation of evidence-based, novel agents into the front-line care of newly diagnosed AML patients
Peripheral T-Cell Lymphoma (PTCL)	**Funding:** ***Dec 2023*** – March 2024	***An updated will be provided mid-2023 prior to the release of any planned budget spend***
B7 homolog 3 protein (B7-H3)	**Funding:** April 2023 – March 2024	Mechanism of action and role of B7-H3 as a potential therapeutic target in solid tumors Current and emerging clinical trial data and treatments related to anti-B7-H3 in advanced or metastatic cancers
Cadherin-6 (CHD6)	**Funding cycle *TBD***	***An updated will be provided mid-2023 prior to the release of any planned budget spend***

References for the gaps identified above can be found in the appendix of this document

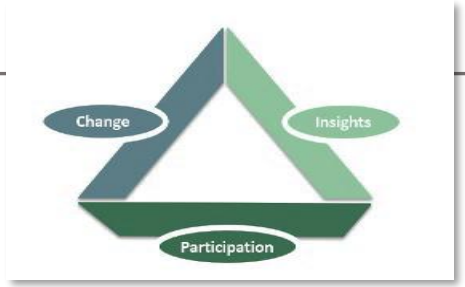
Time-limited Requests for Proposal

Daiichi Sankyo may issue time-limited RFPs in certain areas in the coming months. Time-limited RFPs will indicate requests for tumor-specific educational projects with detailed budget availabilities and date ranges for submission, review, decision, and expected education launches. Further information will be provided at the potential time of release.

Grant Decision Rubric Guide

Daiichi Sankyo thoroughly reviews each grant submitted for our support consideration. While many factors are used to result in the ultimate decision of a grant submission, the following are some of the prominently weighted criteria that will be used to create a comprehensive evaluation of each proposal we receive.

Decision Weighting	Factor
20%	Statement of Purpose and Activity Goals, Gaps, Root Causes, and scientifically accurate Needs Assessment
20%	Educational interventions that align with appropriate learning objectives and follow the accurate adult-learning and instructional design principles that will meet anticipated outcomes
20%	Fair/balanced program nature and demonstrated maintained compliance in overall proposal
15%	Outcomes Assessment Plan
10%	Justification for engagement and ability to reach and effectively sustain engagement with recommended learning audience
10%	Oncology experience, evidence of prior oncology success, and feasibility with recommendations within the proposal
5%	Clear and fair budget justification



Daiichi Sankyo believes educational initiatives are crucial for increasing awareness and improvement toward the topics identified in this packet, as too are the results. **We ask for your consideration of the following recommendations when developing your outcomes plan and assessment**:

- **Participation**: The intent to document and provide the total number, professional background, and regional representation of those who participated.
- **Change**: The intent to predict/provide what will change because of your education, such as overall averaged percentage of knowledge acquisition, pre- versus post-education surrounding the specific learning objectives, and *if relevant,* overall averaged percentage of confidence in any skills taught surrounding the specific learning objectives, and overall averaged percentage of clinical change surrounding the specific learning objectives
- **Insights**: The intent to identify specific clinical insights resulting from the education as well as unique continued barriers to this change
- **Reflection:** The intent to share outcomes with learners as an opportunity to have them reflect and reinforce their learning

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Closing Information

All submissions will be reviewed in compliance to our Standard Operating Procedures and policies, impartially without any preset grant decision(s) made at the release of this packet. Daiichi Sankyo does not support the costs incurred during the preparation of any grant. Daiichi Sankyo publishes Calls for Continuous Grant Submissions/RFPs online through the specific Daiichi Sankyo grants portal. This packet is also posted to the Alliance for Continuing Education for the Health Professions (ACEhp) membership site, and further distributed to all educational providers who have previously submitted and completed successful independent medical education activities within a year from the time of this packet dissemination.

Daiichi Sankyo adheres to the commercial support standards established by the Accreditation Council for Continuing Medical Education (ACCME®). The company also complies with the principles established by the Office of Inspector General (OIG) Compliance Guidance for Pharmaceutical Manufacturers and Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Medical Professionals. https://daiichisankyo.us/corporate-giving-and-support provides information on criterion for submission, our process, and the ways we address some Frequently Asked Questions.

Logistical questions regarding grant submissions can be submitted to OGE-CME@dsi.com and will be channeled to the appropriate therapeutic area manager. As always, we thank you for your contributions to continued education, professional development, and the ultimate elevation of best, personalized care for patients.

Sincerely,
The Medical Proficiency Acceleration Center team,
Daiichi Sankyo, Inc.

Appendix / References

HER2 mBC

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B7-H3

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