

## Daiichi-Sankyo Packaged Requests for Proposal

A Call for Independent Medical Education Grants in Fiscal Year 2021

> 2021 Fiscal year: April 1, 2021-March 31, 2022

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Passion for Innovation. Compassion for Patients.<sup>™</sup>

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## Introduction to this package

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 either 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 call for grant applications, better known as Request(s) for Proposals (RFPs). When published, RFPs will provide details regarding externally referenced educational, clinical, practical, and/or research gaps in specific therapeutic focus areas, along with referenced-driven recommendations for learning audiences, and timeline submission requirements. We invite eligible organizations to log into the grant portal for information on currently available RFPs.

Daiichi Sankyo reserves the right and may publish additional RFPs as the year progresses. *At the current time* this package, issued March 29, 2021, outlines the only Daiichi Sankyo-issued RFPs for Fiscal Year 2021.

## **Two (2) General Call for Grants**

#### HER2 Positive Tumors:

Evaluating current standards of care to advance better patient outcomes

- **Recommended Learner Target:** U.S. based Academic and Community medical oncologists, pathologists, oncology nurses, oncology nurse navigators, pharmacists, and other clinical oncology team members.
- At the current time (and until further notice), Daiichi Sankyo welcomes all non-solicited grants for HER2 education connected to the areas identified below.

Therapeutic Areas Funding is Available	<ul> <li>HER2+ metastatic breast cancer</li> <li>HER2-Low metastatic breast cancer</li> <li>HER2+ metastatic gastric or gastroesophageal adenocarcinoma</li> <li>HER2+ and HER2 mutated non-small cell lung cancer</li> <li>Integration of anti-body drug conjugates within the current management of care in solid tumors, including breast, gastric, and lung</li> </ul>
Submission Terms	Daiichi Sankyo welcomes grant submission throughout the fiscal year with no set deadlines at the time of this RFP publication or unique RFP codes.
Resources	ADEV Group, Multi-Stakeholder Needs Assessment in HER2+ and HER3+ Breast Cancer. 2021.

#### Hematology:

A focus on Epigenetics and T-Cell Lymphomas

- **Recommended Learner Target:** U.S. based Academic and Community medical oncologists, hematologists, hematologist/oncologists, and other clinical oncology team members.
- At the current time (and until further notice), Daiichi Sankyo welcomes general, multi-supported, non-solicited grants for Hematology connected to the areas identified below.

Therapeutic Areas Funding is Available	<ul> <li>Epigenetics that offer potential for new approaches to treating patients with B-cell and T-cell lymphomas, with emphasis on Non-Hodgkin lymphoma (NHL), including peripheral T-cell lymphoma (PTCL) and adult T-cell leukemia/lymphoma (ATL/L)</li> <li>Hematologic antitumor activity, the regulations of gene expressions, and the reactivation of silenced genes resulting in decreased proliferation of EZH2-expressing cancer cells, and the suppression of trimethylation</li> <li>Preference will be given to educational grants that incorporate these areas into <i>broader multi-supported</i> hematologic malignancy programs. All tactical ideas (e.g., broad national CME/IME symposia, CME/IME institutional annual meeting updates) are welcome.</li> </ul>
Submission Terms	Daiichi Sankyo welcomes grant submission throughout the fiscal year with no set deadlines at the time of this RFP publication or unique RFP codes.
Resources	CE Outcomes, Hematology Needs Assessment. 2020.

## Four (4) Timed RFPs

#### Unique RFP Code RFP21003:

## Identifying and Managing Cancer Therapy Induced Interstitial Lung Disease (ILD) and Pneumonitis in Patients:

Ensuring appropriate identification and management for effective personalized care of patients with advancing cancer needs

- **Recommended Learner Target:** U.S. based Academic and community medical oncologists, pathologists, oncology nurses, oncology nurse navigators, pharmacists, and other clinical oncology team members.
- Non-solicited grants received prior to this RFP will still be evaluated and considered.

Available Support	Up to \$200,000 per grant award (Daiichi Sankyo may consider supporting multiple submissions)
Support Educational Needs	<ul> <li>(Daiichi Sankyo may consider supporting multiple submissions)</li> <li>Medication-induced ILD/pneumonitis, understanding and implications. ILD is a broad term for a group of distinct lung disorders, including the most common ILD, idiopathic pulmonary fibrosis, hypersensitivity pneumonitis, and medication-induced ILD.<sup>1</sup> Nonspecific cough, fever, and shortness of breath (dyspnea) are the 3 main symptoms of ILD.<sup>2.3</sup> However, only 1 in 3 cases of ILD has a determined cause. Prevalence rates of medication induced ILD are difficult to assess, and available data may underestimate the prevalence of ILD.<sup>4</sup></li> <li>Understanding medication induced ILD/pneumonitis as a manageable Treatment Emergent Adverse Event (TEAE). While the oncology community has known ILD to be a potential result from utilization of certain anticancer agents, the issue is also being raised with new classes of cancer drugs. In a recent decision, the Foodand Drug Administration (FDA) advised healthcare professionals to "monitor patients regularly for pulmonary symptoms indicative of <i>ILD and/or pneumonitis</i>", including hypoxia, cough, dyspnea, and interstitial infiltrates on radiologic exams.<sup>5</sup> Careful monitoring for and managing ILD/pneumonitis was identified as one of the most challenging adverse events to manage. Survey respondents indicated a self-reported sub-optimal skill in managing toxicities, a rate higher in Nurse Practitioners, Physician Assistants, and Registered Nurses.<sup>7</sup> Health care practitioners show knowledge and awareness of ILD/pneumonitis as a treatment related adverse event from</li> </ul>
	awareness of ILD/pneumonitis as a treatment related adverse event from select cancer therapies, however, lack the confidence and resources to improve monitoring and treatment. While there are published and recommended management protocols in place for ILD/pneumonitis, a need still exists for additional guidance on monitoring and detecting anti-HER-2 therapy induced ILD. <sup>8</sup>
Targeted Objectives	<ol> <li>Review the characteristics, differential diagnosis, and key risk factors of ILD/pneumonitis in patients treated with select cancer therapies</li> </ol>

	<ol> <li>Review incidence rates and recommended symptom management of ILD/pneumonitis in anti-cancer therapies including but not limited to those targeting: antibody-drug conjugates, Immune checkpoint inhibitors, EGFR- TKIs, CDK-4/6 inhibitors, and mTOR inhibitors</li> <li>Review current literature and established protocols for monitoring and detecting medication induced ILD/pneumonitis</li> <li>Identify medication induced ILD/pneumonitis through early monitoring to confidently address manageable events and to implement a safe and best efficacious plan for patients.</li> <li>Discuss ways cancer care team can educate and increase patient and caregiver awareness on characteristics and symptom monitoring of medication induced ILD/pneumonitis</li> </ol>
Interventions	Preference will be given to the following educational interventions:
	<ul> <li>Include the entire care team including oncologists, NPs/PAs, oncology nurses, and pharmacists</li> <li>Focus on clinical performance improvement (e.g. grand rounds, workshops, visiting professor consultation)</li> <li>Incorporates patient and caregiver supplemental resources for symptom recognition and reporting for care team to use and distribute</li> <li>Further, we encourage your submission to outline how you intend to extend the learning across the entire U.S. health system through a resulting, outcomesoriented publication and/or presentation submission plan.</li> </ul>
Submission Terms	<ul> <li>Phase 1 Due: 4/19/2021 (Executive Summaries/Concept)</li> <li>Phase 1 Decision: 4/30/2021</li> </ul>
	<ul> <li>Phase 2 Due: 5/17/2021 (Full grant submission if invited to move forward)</li> <li>Award Decision: 6/16/2021</li> </ul>
	<ul> <li>Award Decision: 6/16/2021</li> <li>Target educational launch date: July-September 2021</li> </ul>
References	<ol> <li>Schraufnagel DE. Interstitial lung disease. Breathing in America: Diseases, Progress, and Hope. New York, NY: American Thoracic Society; 2010:99- 108; Meyer KC. Transl Resp Med. 2014;2(4):1-13).</li> <li>Antoine M, Mlika M. Interstitial Lung Disease. Treasure Island, FL: StatPearls Publishing.</li> <li>Yonemori K, et al. Cancer Sci.2016;107(12):1830-1836</li> <li>Kreuter M, et al. BioMed Res Int. 2015;2015:123876; Schwaiblmair M, et al. Open Resp Med J.2012;6:63-74.</li> <li>FDA Drug Safety Communication. FDA warns about rare but severe lung inflammation with Ibrance, Kisqali, and Verzenio for breast cancer. Sep 13, 2019.</li> <li>AXDEV Group, Multi-Stakeholder Needs Assessment in HER2+ and HER3+ Breast Cancer. 2021.</li> <li>(and 8) Hackshaw MD, Danysh HE, Singh J, et al. Incidence of pneumonitis/interstitial lung disease induced by HER2-targeting therapy for HER2-positive metastatic breast cancer. Breast Cancer Res Treat. 2020;183(1):23-39. doi:10.1007/s10549-020-05754-8</li> </ol>

#### Unique RFP Code RFP21004:

#### HER3

Molecular Diagnostics and Emerging Therapies; relevance of HER3 Expression in Advanced Solid Tumors and building confidence in the clinical value of HER3 Expression in EGFRm NSCLC

- **Recommended Learner Target:** U.S. based Academic and community medical oncologists, thoracic oncologists, pathologists, and nurse practitioners/physician assistant oncologists.
- At the current time (and until further notice), all Fiscal Year 2021 HER3-related educational support will be connected to the needs and targeted objectives of this RFP. This excludes support toward non-solicited, multi-supported, general cancer updates in symposia at annual congresses.
- Non-solicited grants received prior to this RFP will still be evaluated and considered.

Available	Up to \$250,000 per grant award
Support	(Daiichi Sankyo may consider supporting multiple submissions)
Educational Needs	Human epidermal growth factor receptor (HER3) belongs to the human epidermal growth factor receptor (HER) family, which also includes HER1/EGFR/erbB1, HER2/erbB2, and HER4/erbB4. The HER family of receptors has been implicated in pathogenesis of human cancers. HER3 is involved in oncogenesis by activating the PI3K/AKT, MAPK, and JAK/STAT pathways to promote cancer cell survival, proliferation, and progression. HER3 expression can also play a role in resistance to anti-HER2 therapeutic agents. <sup>1</sup> In addition, treatment with EGFR tyrosine kinase inhibitors (TKIs) may increase HER3 expression and consequently its interaction with EGFR. With on-going research and developments in HER3 science, building knowledge and confidence of these advances through targeted, interactive, and readily accessible education is critical in addressing the identified learning gaps by:
	Building Clinical Value of Testing for and Targeting HER3 in oncogenesis Overexpression of HER3 has been seen in a variety of known human cancers including (but not limited to) colorectal, gastric, lung and breast cancers. <sup>2</sup> Currently, there are several on-going clinical trials registered exploring efficacy of therapy interventions in various tumors with HER3 overexpression. <sup>3</sup> Despite this level of activity, a recent survey conducted by the AXDEV Group has shown that 44% of survey respondents lack knowledge and awareness of the latest research related to the role of HER3 in cancer pathology and on average 54% of respondents were unaware the following tumor sites currently being investigated for treatment with HER3 directed antibody-drug conjugates (ADCs): Lung, Colorectal, Breast, Stomach. <sup>4</sup> As more information becomes available around the role of HER3 in oncogenesis, education is needed to identify what HER3 expression means as a targetable biomarker in solid tumors and the role emerging anti-HER3 therapies will have in treatment strategy.
	Examining the unmet need in EGFR-Mutated NSCLC post-TKI therapy Lung cancer is the most common cancer and leading cause of cancer death. <sup>5</sup> Non- small cell lung cancer (NSCLC) accounts for approximately 84% of all lung cancers. <sup>6</sup> Over 60% of NSCLC expresses EGFR, a transmembrane protein with cytoplasmic kinase activity that transduces growth factor signaling. <sup>7</sup> First- or second-generation EGFR-TKIs are standard first-line therapy for advanced EGFR- mutant NSCLC. <sup>8,9</sup> Furthermore, the third-generation EGFR-TKI is an optimal treatment for NSCLC with a secondary Thr790Met point mutation (T790M) in

	EGFR, which is a gatekeeper mutation for first- and second-generation EGFR TKIs. <sup>9</sup> Despite initial benefits, progression inevitably occurs after about 10 months. <sup>8</sup> Treatment options are more limited to chemotherapy or immunotherapy for NSCLC patients who develop resistance to first- and second-line EGFR TKIs. <sup>10</sup> Clinical resistance to EGFR TKIs has been linked to multiple gene-based mechanisms, and in many cases, the underlying cause remains unknown. Many EGFR-mutated NSCLCs, however, show some level of HER3 expression. <sup>9</sup> New approaches and targets are needed to overcome resistance. Despite the association of HER3 expression with reduced survival in NSCLC, no HER3 directed anticancer therapies are currently approved. <sup>11-13</sup> Education is needed to examine the molecular approaches to testing HER3 expression, explain the expression pattern of HER3 physiologically and pathologically in the progression of EGFR-mutated NSCLC, and evaluate the role of HER3 in the development of resistance to EGFR TKIs.
Targeted Objectives	<ol> <li>Establish the mechanism of disease of HER3 and its role as a valuable biomarker in oncogenesis</li> <li>Explain the value of testing for HER3 overexpression while also reviewing the pattern of HER3 in the progression of advanced/metastatic solid tumors.</li> <li>Review the molecular determinants and diverse mechanisms that drive TKI acquired resistance including those related to HER3 expression (e.g., EGFR C797s mutation, MET amplification, and PIK3CA), and those not related to HER3 and evaluate the unmet needs that exist with current therapeutic options</li> <li>Review the clinical data (efficacy and safety) of current and emerging therapies (including HER3 directed ADCs) used in EGFR TKI-resistant NSCLC, and where these emerging therapies would fit in the treatment paradigm.</li> </ol>
Interventions	<ul> <li>Preference will be given to the following educational interventions:</li> <li>Digital formats that utilize visual and interactive demonstrations that help explain disease state and mechanism of action.</li> <li>Internet based, interactive faculty led discussion panels including clinical updates and relevancy to practice.</li> <li>Further, we encourage your submission to outline how you intend to extend the learning across the entire U.S. health system through a resulting, outcomesoriented publication and/or presentation submission plan.</li> </ul>
Submission Terms	<ul> <li>Phase 1 Due: 4/19/2021 (Executive Summaries/Concept)</li> <li>Phase 1 Decision: 4/30/2021</li> <li>Phase 2 Due: 5/17/2021 (Full grant submission if invited to move forward)</li> <li>Award Decision: 6/16/2021</li> <li>Target educational launch date: July-September 2021</li> </ul>
References	<ol> <li>Karachaliou N, Lazzari C, Verlicchi A, Sosa AE, Rosell R. HER3 as a Therapeutic Target in Cancer. <i>BioDrugs</i>. 2017 Feb;31(1):63-73. doi: 10.1007/s40259-016-0205-2. PMID: 28000159.</li> <li>Lyu H, Han A, Polsdofer E, Liu S, Liu B. Understanding the biology of HER3 receptor as a therapeutic target in human cancer. Acta Pharm Sin B. 2018 Jul;8(4):503-510. doi: 10.1016/j.apsb.2018.05.010. Epub 2018 Jun 2. PMID: 30109175; PMCID: PMC6090011.</li> </ol>

3	<ol> <li>NIH: National Library of Medicine (NLM); 2020. Accessed March 8, 2021. Clinicaltrials.gov</li> </ol>
4	<ul> <li>AxDEV Group, Multi-Stakeholder Needs Assessment in HER2+ and HER3+ Breast Cancer. 2021.</li> </ul>
5	5. Low J, et al. Ther Adv Med Oncol. 2019; 11: PMC6716180.
	6. American Cancer Society. Key statistics for lung cancer.
	https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html. Accessed
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	<ol><li>da Cunha Santos G, et al. Ann Rev Pathol. 2011; 6:49-69.</li></ol>
8	B. Mok TS, Wu Y, Ahn M, Garassino MC, Kim HR, Ramalingam SS, et al.
	Osimertinib or platinum-pemetrexed in EGFR T790M positive lung cancer. <i>N Engl J Med</i> . 2017;376(7):629–40.
9	<ol> <li>Wu SG, Shih JY. Management of acquired resistance to EGFR TKI-targeted therapy in advanced non-small cell lung cancer. <i>Mol Cancer</i>. 2018 Feb</li> </ol>
	19;17(1):38. doi: 10.1186/s12943-018-0777-1.10. Sequist L, et al. <i>Sci Transl Med</i> . 2011;3(75):75ra26.)
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	1. Chiu CG, et al. Ann Surg. 2010;251[6]:1107-1116.
	2. Fuchs IB, et al. Anticancer Res. 2006;26[6B]:4397-4401.
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#### Unique RFP Code RFP21005:

#### Trophoblast cell surface antigen 2 (TROP2):

Sequencing of TROP2 ADCs in Advanced/Metastatic NSCLC patients with nonactionable genomic alterations

- **Recommended Learner Target:** U.S. based academic and community medical oncologists, pathologists, and NPs/PAs
- At the current time (and until further notice), all Fiscal Year 2021 TROP2-related educational support will be connected to the needs and targeted objectives of this RFP. This excludes support toward non-solicited, multi-supported, general cancer updates in symposia at annual congresses
- Non-solicited grants received prior to this RFP will still be evaluated and considered.

Available	Up to \$250,000 per grant award
Support	(Daiichi Sankyo may consider supporting multiple submissions)
Educational Needs	Lung cancer is the most common cancer and leading cause of cancer death. <sup>1</sup> Most NSCLC carcinomas do not have an actionable genomic alteration; 33% of patients with adenocarcinoma NSCLC and 37% with squamous cell carcinoma NSCLC do not have actionable genomic alterations. <sup>2,3</sup> In the case of non-actionable genomic alterations, the NCCN recommends the use of PD-L1 immune checkpoint inhibitors and platinum-containing chemotherapy regimens in the 1L and 2L setting. <sup>4</sup> While PD-L1 inhibitor-based therapy can improve survival for patients with advanced NSCLC without actionable genomic alterations (mOS <30 months), many patients have an initial tumor response, but most progress (mPFS <17.2 months). <sup>5</sup> Ongoing research includes the identification of other more accurate, predictive biomarkers that will allow better patient selection, characterization of mechanisms of resistance and determining treatment strategies to overcome resistance and optimize efficacy. <sup>1</sup> There are currently multiple ongoing clinical trials studying the use of

	TROP2-targeted agents in the treatment of NSCLC across different treatment line settings. <sup>6</sup> Despite recent clinical progress, there are critical gaps that exist, including but not limited to: Understanding TROP2 as a biomarker in NSCLC. TROP2 is a transmembrane glycoprotein that is overexpressed in many cancers. <sup>7</sup> TROP2 expression has been associated with poor overall and disease-free survival in several types of solid tumors. TROP2 expression has been observed in up to 64% of adenocarcinoma and up to 75% of squamous cell carcinoma NSCLC. <sup>7-11</sup> As TROP2 is a clinically relevant cell surface antigen among several solid tumor types, its overexpression on cancer cells makes it an ideal candidate for targeting by specific therapies. One targeted approach involves the use of antibody-drug conjugates (ADCs). <sup>12</sup> Examine ways to sequence current and emerging treatment options after relapsed/refractory NSCLC without actionable genomic alterations. As tumors often recur and patients progress after PD-L1 immune checkpoint inhibitors (IO) and platinum-containing chemotherapy regimens in the 1L setting, emerging evidence suggests that TROP2 targeted ADCs may be an optimal treatment choice after progression with IO and platinum-containing chemotherapy. Innovative educational tools and approaches are needed to help with not only applying emerging evidence but differentiating TROP2 ADCs in the context of patients' personalized treatment needs and improving patient management. Further clarity and understanding are needed on sequencing emerging therapy, upon approval, and their place in the treatment paradigm. Education will, also, be needed in differentiating the emerging TROP2 ADCs including but not limited to efficacy of agents, tolerability, ease of administration schedule, and ADC technology.
Targeted Objectives	<ol> <li>Explore TROP2 as a biomarker in NSCLC, its role in oncogenesis, the clinical relevance of TROP2 as a cell surface antigen among several solid tumors and the mechanism of action of TROP2 targeted ADCs</li> <li>Examine the current treatment options in advanced NSCLC patients without actionable genomic alterations that have either relapsed or are refractory to platinum-based chemo and anti-PD-1/PD-L1 immunotherapy (IO), and explore the role that emerging therapy will have in later line (2L and 3L) treatment plans to address the unmet needs of patients with disease progression</li> <li>Effectively differentiate the clinical data including efficacy, tolerability profiles, dosing regimen as well as ADC technology for the TROP2 ADCs and interpret and integrate these findings in identifying NSCLC patients who may benefit from each of these emerging therapies</li> </ol>
Interventions	Preference will be given to innovative, internet based, interactive faculty led discussion panels including clinical updates and relevancy to practice. Further, we encourage your submission to outline how you intend to extend the learning across the entire U.S. health system through a resulting, outcomes-oriented publication and/or presentation submission plan.
Submission Terms	<ul> <li>Phase 1 Due: 4/19/2021 (Executive Summaries/Concept)</li> <li>Phase 1 Decision: 4/30/2021</li> <li>Phase 2 Due: 5/17/2021 (Full grant submission if invited to move forward)</li> <li>Award Decision: 6/16/2021</li> </ul>

	Target educational launch date: July-September 2021
References	<ol> <li>Low J, et al. Ther Adv Med Oncol. 2019; 11: PMC6716180.</li> <li>Schiller JH, et al. <i>N Engl J Med</i>. 2002;346(2):92-98.</li> <li>Scagliotti GV, et al. <i>Cancer Treat Rev</i>. 2015;41(6):465-475.</li> <li>NCCN Clinical Practice Guideliens in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.4.2021.</li> <li>Omori S, et al. <i>J Clin Oncol</i>. 2019;37(15_suppl):e14732.</li> <li>Zaman S, et al. <i>OncoTargets and Therapy</i>. 2019;12:1781-1790.</li> <li>Inamura K, <i>et al</i>. Association of tumor TROP2 expression with prognosis varies among lung cancer subtypes. <i>Oncotarget</i>. 2017;8(17):28725-28735.</li> <li>Pak M, <i>et al</i>. Significance of EpCAM and TROP2 expression in non-small cell lung cancer. <i>World J Surg Oncol</i>. 2012;10:53.</li> <li>Li Z, <i>et al</i>. TROP2 overexpression promotes proliferation and invasion of lung adenocarcinoma cells. <i>Biochem Biophys Res Commun</i>. 2016;470:197-204.</li> <li>Liu T, <i>et al</i>. Overexpression of TROP2 predicts poor prognosis of patients with cervical cancer and promotes the proliferation and invasion of cervical cancer cells by regulating ERK signaling pathway. <i>PLoS One</i>. 2013;8:e75864.</li> <li>Shvartsur A, Bonavida B. <i>Genes Cancer</i>. 2015;6(3-4):84-105</li> <li>Peters C, Brown S. Antibody-drug conjugates as novel anti-cancer chemotherapeutics. <i>Biosci Rep</i>. 2015;35(4):e00225. doi:10.1042/BSR20150089.</li> </ol>

#### Unique RFP Code RFP21006:

### Tenosynovial Giant Cell Tumor (TGCT):

Elevating multidisciplinary care to advance the best care options for patients

- **Recommended Learner Target:** U.S. based academic and community medical oncologists, oncology-focused orthopedic surgeons
- At the current time (and until further notice), all Fiscal Year 2021 TGCT-related educational support will be connected to the needs and targeted objectives of this RFP, excluding support toward an independent medical education symposium at a major conference(s) related to TGCT scientific conversations.
- Non-solicited grants received prior to this RFP will still be evaluated and considered.

Available	Up to \$300,000 per grant award
Support	(Daiichi Sankyo may consider supporting multiple submissions)
Educational Needs	Evidence suggests that extensive surgical resection of the hypertrophic synovium and multiple soft tissue masses for diffuse TGCT has and continues to result in high rates of recurrence, <sup>1</sup> with a risk of significant decline in quality of life (QOL). At times, some patients result in a partial loss of function of the affected joint and may also experience perioperative morbidity and secondary arthrosis. <sup>2</sup> As such, providing alterative care plans to patients with TGCT has been a paramount discussion in the clinical community for some time. TGCT is associated with characteristic cytogenetic abnormalities resulting in the overexpression of CSF1 <sup>3</sup> and there have been advances (approved and emerging/experimental) in therapeutic research in systemic therapies targeting CSF1. These advances bring forward effective clinical activity and manageable toxicity, notwithstanding

	needed attention toward manageable but potentially fatal side effects. These advances, however, have exposed several other critical gaps, including but not limited to:
	Recommendations in current guidelines for multidisciplinary work as crucial to addressing care. Personalized patient journeys require that patient decisions are impacted by multiple healthcare professionals (HCPs). There continues to be a chasm between medical oncologists and oncology-focused orthopedic surgeons who need to work in tandem as the initial care support for patients with TGCT.
	The significant impact before- and after-surgery care has on patient outcomes is a topic rarely of primary focus in education. As tumors often recur, emerging evidence suggests adjuvant treatment options in recurrent nonresectable cases may amplify patient outcomes when added to a care plan that includes the surgical Standard of Care.
	Innovative educational tools and approaches are needed to help address multidisciplinary, interprofessional connectivity, the adoption of emerging evidence in a timely manner, and improving patient management. Evidence suggests that HCPs who manage this rare disease desire more education but have few opportunities to collect the right information and credits, outside of major conference activities, at the right time to address when patients present with TGCT. Further, cognitive biases may drive HCPs who diagnose and manage patients with TGCT among other common diseases to take a more common, but less efficacious approach, risking timely referrals, presenting all options to patients, addressing patient questions, and monitoring patient progress. Leveraging the innovative tools can aid patients toward the most appropriate care plan and spotting patterns in data to be addressed at the right time.
Targeted Objectives	<ol> <li>Explain the scientific rationale and clinical evidence for the use of targeted systemic options in the management of TGCT</li> <li>Examine the safety and efficacy of care to proactively identify and manage side effects</li> <li>Discuss and monitor the impact and maintenance of therapy in combination with surgery, prior to and after the surgical intervention.</li> <li>Adopt effective multidisciplinary approaches for localized and diffuse TGCT to optimize the diagnosis and management of patient outcomes</li> </ol>
Interventions	Preference will be given to innovative, certified educational tools (e.g. Artificial Intelligent-powered concepts) that provide education and a network to allow for seamless, continuous learning across the medical oncologists and oncology-focused orthopedic surgeons. Further, we encourage your submission to outline how you intend to extend the learning across the entire U.S. health system through a resulting, outcomes-oriented publication and/or presentation submission plan.
Submission Terms	<ul> <li>Phase 1 Due: 4/19/2021 (Executive Summaries/Concept)</li> <li>Phase 1 Decision: 4/30/2021</li> <li>Phase 2 Due: 5/17/2021 (Full grant submission if invited to move forward)</li> <li>Award Decision: 6/16/2021</li> <li>Target educational launch date: July-September 2021</li> </ul>

References/ Sources	<ol> <li>Griffin, Anthony et al. Long-term outcome of the treatment of high-risk tenosynovial giant cell tumor/pigmented villonodular synovitis with radiotherapy and surgery 2012 Oct 1;118(19):4901-9. doi: 10.1002/cncr.26529. Epub 2012 Jan 26.</li> </ol>
	<ol> <li>Brahmi, M., Vinceneux, A. &amp; Cassier, P.A. Current Systemic Treatment Options for Tenosynovial Giant Cell Tumor/Pigmented Villonodular Synovitis: Targeting the CSF1/CSF1R Axis. Curr. Treat. Options in Oncol. 17, 10 (2016).</li> </ol>
	<ol> <li>Brahmi, M., Vinceneux, A. &amp; Cassier, P.A. Current Systemic Treatment Options for Tenosynovial Giant Cell Tumor/Pigmented Villonodular Synovitis: Targeting the CSF1/CSF1R Axis. Curr. Treat. Options in Oncol. 17, 10 (2016).</li> </ol>
	<ul> <li>Wicks, Paul. From A to Zebra: Data-driven strategies for training AI to understand rare diseases. MobileHealthNews. February 28, 2020.</li> <li>CE Outcomes TGCT Needs Assessment, 2020.</li> </ul>

## **Instructions for Timed RFP Submissions**

Daiichi Sankyo has determined the educational submissions are crucial for increasing awareness and improvement upon the topics identified in these RFPs. We remain open to additional evidence-based perspectives that provide complementary gaps and outcomes that are deemed most appropriate, with mindfulness of the following outcomes recommendations:

- 1. The intent to document and provide the total number, professional background, and regional representation of those who participated
- 2. The intent to predict/provide what will change because of your education, in the context of:
  - Overall averaged percentage of knowledge acquisition, pre- versus posteducation surrounding the objectives you deem appropriate
  - Overall averaged percentage of confidence in any skills taught, as demonstrated by the objectives you deem appropriate
  - Overall averaged percentage of clinical change, as demonstrated by the objectives you deem appropriate
- 3. The intent to predict the magnitude of change
- 4. The intent to identify any continued barriers to this change

Additionally, we recommend the following Outcomes guidance chart that could be used in the development and evaluation of objectives you might submit in response to these RFPs:

	Therapeutic Area	Improved Knowledge of Scientific Information	Improved Confidence in Emerging Data	Improved Competence in Incorporating Science into Real World Cases	Elevated and/or Improved Practice Change
Call for Grants	HER2 Tumors				
	Hematology				
RFPs	Induced ILD				
	HER3				
	TROP2				
	TGCT				

Daiichi Sankyo does not support the costs incurred during the preparation of any grant or responses to these RFPs. Daiichi Sankyo publishes RFPs online through our grants portal and through the Alliance for Continuing Education in the Health Professions (ACEhp). This RFP is also distributed to all educational providers who have previously completed successful independent education activities supported by Daiichi Sankyo within a year from the time of this RFP publication.

Daiichi Sankyo makes available funding for Independent Medical Education that ultimately benefits elevated patient care. 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 PharmaceuticalManufacturers and Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Medical Professionals. <u>https://dsi.com/continuing-medical-education-grants</u> provides information on criterion for submission, our process, and the ways we address some Frequently Asked Questions.

#### The Process for the Daiichi Sankvo RFP Submission(s)

- <u>Phase 1</u>: Initial Executive Summary to include one-to-two page(s) of a summarized gap analysis and description of the educational design, tactic, implementation, and outcomes plan to be submitted to <u>OGE-CME@dsi.com</u> with the subject line "2021 RFP [insert RFP Code & your personalized title]"
- <u>Phase 2</u>: If selected to move forward, you will be invited to submit a complete grant request to DSI.com, under "Responsibility," and "Independent Medical Education Grants" choosing either CME or Non-CME, as relevant for your grant submission, then selecting the appropriate RFP dropdown item when starting the submission process. Again, we ask that you title you grant as *"2021 RFP [insert RFP Code & your personalized title]"*

Daiichi Sankyo welcomes all accredited or accredited-partnered educational providers to respond to these requests. All submissions will be reviewed in compliance with our Standard Operating Procedures and policies, impartially without any preset grant decision(s) made at the release of these RFPs.

Logistical questions regarding these RFPs can be submitted to <u>OGE-CME@dsi.com</u> 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.