# Pembrolizumab and berahyaluronidase alfa (Subcutaneous Pembrolizumab)

We are currently accepting proposals for the Subcutaneous Pembrolizumab Investigator Initiated Studies Program (IISP). Please be aware that this is a highly competitive process.

**To help to prepare a successful proposal, we are providing the following guidance:**

- Please contact your local Regional Medical Scientific Director (RMSD, US only) or country specific liaison for any guidance pertaining to your specific concept prior to its submission, to ensure that it falls within the scope and interest of the Investigator Initiated Studies Program (IISP).
- Carefully review the Areas of Interest (AOI) below. Proposals that are not within the scope of these AOIs may be rejected without further review. Occasionally, we receive proposals out of the AOIs that represent "out of the box" thinking and are ultimately of great interest. If you believe this may apply for your proposal, please review with your RMSD or appropriate liaison prior to submission.
- Please include documentary evidence of successful and timely accrual and publication of investigators' studies in similar indications where possible. Feasibility is carefully considered in our assessment process.
- Combinations with non-MSD agents may be considered. Proposals should only include Subcutaneous Pembrolizumab monotherapy or combinations in indications which are approved.
- The Program encourages less experienced investigators to seek guidance from a mentor prior to submitting IISP proposals. If working with a mentor please also provide their CV where possible, along with a detailed letter from the mentor describing the mentoring plan.
- Proposals may consider safety among their endpoints, but this needs to be relevant to the implementation of a Subcutaneous Pembrolizumab service. Solely reporting of side effects of Subcutaneous Pembrolizumab, which are already well documented, is not in scope.
- Proposals for which the primary objectives are translational are outside of the current MISP AOIs.

- The program requests that investigators specify how they will include populations that have historically had limited access to care.

Please note that IISP proposals competing with or duplicating any company sponsored trial for Subcutaneous Pembrolizumab will not be supported.

The IISP review is a competitive process. Decisions will be made on the basis of scientific/clinical merit and strategic fit, as well as feasibility.

Please be sure to abide by the timelines for this process as outlined below when submitting applications.

For investigators outside of the US, please contact your MSD country liaison for relevant requirements and timelines.

**Special Note: Diversity & Inclusion and Patient Engagement**

We seek to foster diverse and inclusive representation and patient engagement within the individual Areas of Interest for each tumor type. We encourage study proposals across our Program which, in addition to demonstrating scientific merit, also take into consideration the following:

- Outcome disparities in populations that have historically had limited access to care
- Inclusion of non-academic programs/institutions
- Involvement of under-represented regions or countries

**Subcutaneous Pembrolizumab with Berahyaluronidase alfa (SC Pembrolizumab) 2025 AOIs for MISP Studies**

Main AOIs:

1. Patient and healthcare professional (HCP) reported outcomes including experience, satisfaction, preference, HRQOL in different care settings.
2. Logistics & implementation of SC pembrolizumab in different care settings.
3. Exploring the economic and efficiency impact of SC pembrolizumab in different care settings.

Care settings may include: hospital or clinic-based oncology infusion centre, other hospital based administration site made feasible by SC pembrolizumab, “last-mile” and

community based administration site, home administration by HCP or self-administration* with appropriate training and oversight by a HCP.

* If considering self-administration by patients at home, please alert your country representative/RMSD as further discussion with the MISP team is necessary.

**Please note that SC pembrolizumab can only be used for approved indications.**

Particular scenarios in which the above areas may be investigated:

1. Nurse led research would be welcome.

2. Specialized infusion centre versus last mile (community based) facility.

3. Urban versus rural service.

4. Home administration by HCP and/or self-administration* (including use of Tele-medicine).

5. Patients receiving SC pembrolizumab in different age and lifestyle groups e.g. working versus non-working patients, patients with childcare responsibilities.

6. Patients receiving SC pembrolizumab in different healthcare systems e.g. US versus ex-US, insurance-based systems versus centrally funded health service.

7. Administration of SC pembrolizumab in specific treatment scenarios e.g. combination with local therapies such as intravesical therapy and peri-operative treatment.

* If considering self-administration by patients at home, please alert your country representative/RMSD as further discussion with the MISP team is necessary.