



Access to Transplantation

Start-up Program for Pediatric BMT Centers in LMICs



PURPOSE

As part of the DKMS Access To Transplantation (ATT) program, the Start-up Program for Pediatric BMT Centers intends to enable partners in LMICs (low- and middle-income countries) to locally offer safe and effective low-risk Hematopoietic Stem Cell Transplantation (HSCT) with a matched family donor for children suffering from Severe Thalassemia (ST) or Sickle Cell Disease (SCD) in a sustainable manner. This shall be facilitated by taking relatively inexpensive approaches in adequate facilities that meet evidence-based quality standards pertinent to the expected HSCT case mix.

The common goal shall be to reach 20 allogeneic transplantations during the first two years with three BMT rooms, using a cloud-based IT platform. As of the third year, 20 transplantations annually shall be reached. Partners must be willing to share outcome data and the costs per transplantation. Further, they should have the ambition to look into international accreditation according to [FACT/JACIE standards](#).

The ATT program is funded and administered by DKMS.

TARGET GROUP/ BENEFICIARIES

The program is open to all hospitals and tertiary care centers in haemoglobinopathy-prone areas that provide standard of care for patients with Severe Thalassemia or Sickle Cell Disease or cooperate with centers that offer such care. Responsible body for the pediatric BMT center must be a non-profit corporate body or a legal entity of public law. Centers from all countries classified as low- and middle-income country by the World Bank are invited to apply.



SCOPE OF THE PROGRAM

The program covers a time period of several years and is geared to the specific needs of the respective center.

The Program offers

- Needs assessment/ gap analysis

- Advise on the infrastructural set-up of the pediatric BMT Unit
- Advise on the preparation to meet key-requirements to take up low-risk allogeneic HSCT with a matched family donor for children suffering from Severe Thalassemia or Sickle Cell Disease, including but not limited to
 - Creating Standard Operating Procedures (SOP)
 - Training, education, and progress verification
 - Sustainable plan development
 - Implementation strategy
 - Project management advice
 - Support in accessing cloud-based IT platform
 - Advice for best start-up patient identification and assessment
- Onsite consulting for the first two transplantations facilitated by an experienced Hematologist and a BMT Nurse for up to 4 weeks.
- Continuing medical online advice for a period of three years after the first transplantations. If the goal of 20 allogeneic HSCTs within the first two years may not be reached, DKMS support for the third year may be re-considered.
- Access to an international BMT network focusing on safe and effective HSCT in resource-limited settings.
- Support in gaining scientific credibility.
- Access to free HLA typing from DKMS Life Science Lab (high-throughput typing with DKMS' current standard typing profile) for selected patients and their close family members (siblings and parents only).

In addition to the program, DKMS may consider

- To cover parts of the treatment costs for transplantation during the start-up phase.
- To provide infrastructural funding support.



COMMITMENT OF BENEFICIARIES

The program covers a large scope of support over several years, depending on the specific local needs. Beneficiaries are hence obliged to commit to defined requirements and regular reporting during the entire program.

Before the start-up of the first transplantations, beneficiaries must be

- Willing to close identified gaps to meet the key-requirements for taking up low-risk allogeneic HSCT
- Willing to set up a cloud-based IT infrastructure for patient selection and online support
- Willing to enter into a formal agreement with DKMS

After the start-up of the first transplantations, beneficiaries must

- Be willing to frequently give case presentation (weekly after first transplants; later at longer intervals)

- Be willing to share outcome data (CIBMTR or EBMT registries)
- Share information on the cost per transplantation
- Report on the progress, challenges and learnings of operating the BMT Unit
- Commit to applying for FACT-JACIE international accreditation within 2-5 years of startup.



APPLICATION PROCESS

The application process is divided in two steps: Firstly, an expression of interest which may, after a positive evaluation by DKMS, be followed by a full application. Provided documents will be reviewed and evaluated by the *Medical Review and Advisory Group* within an anticipated timeframe of 6 or 10 weeks after the application deadlines respectively. DKMS will inform the applicant in writing.

1. Sketch (Expression of interest)

Centers interested in formally applying for the Start-up Program for Pediatric BMT Centers must as a first step hand in a sketch as an expression of interest. This must be signed by a medical responsible person, preferably the hospital management.

The sketch shall not exceed 5 pages and must include the following:

1. Organizational Form and Structure of the Center
 - a. Statement that the center is a non-profit corporate body or a legal entity of public law, and proof thereof
 - b. Overview of medical departments, supporting staff etc.
2. Country- and Center-Specific Statistics
 - a. Relevant statistics on the population and health care services
 - b. Prevalence of severe hemoglobinopathies
 - c. Details about the centers patient base and provided standard of care for SCD or ST (as applicable). Information on availability of an outpatient clinics for these patients.
3. Patients/ Staff/ Stakeholders
 - a. How do patients currently access HSCT?
 - b. Which professionals are currently available at the center to potentially engage in HSCT (physicians & nurses)? How good are their English language skills?
4. Overall Start-up Motivation/ Strategy/ Approach
 - a. Reasons for the application, specific aims and objectives of the organization.

The sketch will be reviewed and evaluated by DKMS. If deemed eligible, the center will be invited to submit a full application based on a separate file provided by DKMS. Additional queries relating to the sketch may be raised and shall be addressed with the application.

2. Full Application (by invitation only)

The application must be submitted in English language jointly with the cover sheet. It must cover all relevant details as required (separate checklist to be shared by DKMS).

The application checklist below should be used to ensure that the application is complete prior to submission. Incomplete applications will not be considered.

THE COMPLETE APPLICATION MUST INCLUDE THE FOLLOWING:

1. Cover Sheet (as provided by DKMS)
2. Checklist as provided by DKMS
3. Founding document/s that confirm the entity's non-profit status (e.g. memorandum of incorporation, statutes, articles of association) or in case of a public center a confirmation letter of the governing authority. English translations of documents to be included, if applicable.
4. Outlook for the next three years including a business plan
5. Answers to DKMS queries relating to the sketch, if applicable.



DEADLINES

Applications should be submitted to att@dkms.de. For each step, please note the following deadlines:

Sketches are accepted on a rolling basis. An evaluation shall be performed within an anticipated timeframe of 6 weeks after submission, and the results will be communicated to the applicant in writing.

Full applications must be received within 3 months after invitation by DKMS. An evaluation shall be performed within an anticipated timeframe of 10 weeks after submission, and the results will be communicated to the applicant in writing.

Any application failing to meet the requirements of the program will be judged ineligible. Only institutions that fulfil the applicable legal requirements from non-profit / charity law may be chosen as recipients under the program.

Even if all the conditions for funding stated in these guidelines are met by an applicant, there is no legal entitlement to funding. The decision on funding lies solely with the DKMS selection committee, which may justify its decision to decline funding, however, it is not under obligation to do so.

Applications will be treated as confidential documents.



CONTACT

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