

Regional Project Concept Template (Category A)

(6)

The information contained in this template should be uploaded to the PCMF IT platform by the Chair of the relevant regional cooperative agreement or the NLO of the Member State submitting the concept by **31 May 2012** at the latest. Based on this information the IAEA will assess whether this project concept is in line with the TC quality criteria and requirements. Concepts positively appraised will be further developed into full project documents during the design phase.

Region:	Pakistan		
Regional/Cooperative agreement (if applicable)	NIL	Priority no. given by regional/cooperative agreement (for concepts proposed under the auspices of regional cooperative agreements)	
Title	Use of Thyrotropin Alpha in the management of metastatic differentiated thyroid cancer patients		
Field of activity	Nuclear Medicine		
Regional project category¹	<input type="checkbox"/> <i>Transnational</i> <input checked="" type="checkbox"/> <i>*Regional standard setting</i> <input type="checkbox"/> <i>Capacity building for developing countries</i> <input type="checkbox"/> <i>Joint TC activities with a regional or international entity</i>		
Names and contact details of project counterparts and counterpart institutions (starting with the main counterpart)	<p>Dr Wajiha Nasir, Senior Medical Officer in Nuclear Medicine Department of Nuclear Medicine, Oncology and Radiotherapy Institute (NORI), G-8/3, P.O. Box 1590, Islamabad, Pakistan. Tel no (off): 92-51-9260611-15, Fax (off): 92-51-9260616, email: wajihanasir2003@hotmail.com</p> <p>Dr Shazia Fatima, Principal Medical Officer in Nuclear Medicine Department of Nuclear Medicine, Oncology and Radiotherapy Institute (NORI), G-8/3, P.O. Box 1590, Islamabad, Pakistan. Tel no (off): 92-51-9260611-15, Fax (off): 92-51-9260616</p> <p>Dr Javaid Irfan, Director, Oncology and Radiotherapy Institute (NORI), G-8/3, P.O. Box 1590, Islamabad, Pakistan. Tel no (off): 92-51-9260611-15, Fax (off): 92-51-9260616.</p>		
Analysis of regional Gap / Problems/needs	<p>Cancer of the thyroid is the most common endocrine malignancy globally. Hence its effective management is very much mandatory. In the course of management of thyroid cancer (CA) patients near-total or total thyroidectomy is usually performed, followed by radioiodine (I131) treatment to remove any remnant of normal thyroid tissue and microscopic residues of malignant tissue. Prior to radioiodine remnant ablation, serum TSH elevation (at least 25 m IU/ ml) is necessary to promote uptake of radioiodine by thyroid cells or thyroid cancer cells and to achieve optimal sensitivity of serum thyroglobulin testing. Elevation of TSH may be achieved by withholding of synthetic thyroid hormone medication.</p> <p>In some metastatic differentiated thyroid cancer (DTC) patients, TSH never rises adequately after thyroidectomy and even after intake of I131 in therapeutic doses. In such cases Thyrotropin alpha can be used prior to therapeutic I131 therapy. Thyrotropin alpha aided radioiodine (I 131) treatment of patients with inoperable locally aggressive or distant metastatic DTC - still considered experimental.</p> <p>In Pakistan this drug is not in routine use due to its very high cost. So far very few studies are done globally in which thyrotropin alpha is used for the management of metastatic CA thyroid. According to one study published in internet its use reduces the risk of tumor stimulation and its sequel due to short TSH elevation time (elimination half life: 25 ± 10 hours). On the other hand according to some other studies Thyrotropin alpha usage is not</p>		

¹ See the document entitled "Policy and Procedures for TC Regional Projects" at: http://pcmf.iaea.org/DesktopModules/PCMF/docs/2014_15_Docs/notes/Regional_TC_Project_Policy.pdf.

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	recommended for metastatic CA thyroid patients due to its stimulatory effect on tumor growth.
Why should it be a regional project?	Thyroid cancer is one of the most common endocrine malignancies through out the world. Overall, about 5% of patients with thyroid cancer have metastases beyond the cervical or mediastinal area on initial presentation, 2-3% of patients with papillary thyroid cancer and 11% of patients with follicular thyroid cancer. Treatment of metastatic patients is usually difficult and prolonged. Thyrotropin alpha can be tried in such patients to see its efficacy and beneficial effects on out come of such patients.
Stakeholder analysis and partnerships	At NORI such patients will be managed and evaluated through follow up scans, S.Tg, ATg levels and with other investigations (like CT scan, ultrasound etc) if required. PINSTECH, Nilore, Pakistan will be the institute from where we get I131 on payment
Overall objective (or developmental objective)	Main objective of the study is to use Thyrotropin alpha in the management of metastatic differentiated thyroid cancers (papillary and follicular) patients prior to radioactive iodine therapy and follow I131 scans. Atleast 50 patients should be included in this study Thyrotropin alpha is a newly approved drug and lot of work has to be done to prove its role(stimulatory or nonstimulatory effects) in the management of metastatic CA thyroid patients. If this drug proves to be effective, it opens new ways for the management of thyroid metastatic cases while maintaining their quality of life (avoiding hypothyroid symptoms especially in follow up scans).
Analysis of objectives	Metastatic CA thyroid patients managed with Thyrotropin alpha aided I131 therapy will be evaluated through clinical improvement of condition of patient, follow up I131 scans and with tumor markers. If thyrotropin alpha shows better effects in the management of metastatic CA thyroid patients then it will be a big achievement.
Role of nuclear technology and the IAEA	I131 is a radioactive material used in the management of thyroid cancer patients. Thyrotropin alpha aided I131 therapy proves to be very effective in post surgical thyroid remnant ablation and for diagnostic evaluation of thyroid cancer patients without making patient hypothyroid. Thyrotropin alpha supplemented radioiodine (I 131) treatment of patients with inoperable locally aggressive or distant metastatic DTC - still considered experimental. Thyrotropin alpha is not routinely used in most of the medical centers of Pakistan due to its high cost. By the sponsorship of IAEA we can use Thyrotropin alpha in the management of our metastatic CA thyroid patients. If this drug proves to be effective in their management then this will set new directions in the treatment of matastatic thyroid cancer patients
Project duration	<i>Project can be started with in few months and approximate duration of project will be 4-5 yrs</i>
Requirements for participation	Nuclear medicine department with hot lab, Thyrotropin alpha kits, Radioactive iodine, lab facilities for TFTS, Thyroglobulin and antithyroglobulin levels, Isolation rooms to retain patients after receiving therapeutic I131 doses, Medical physics department, Gamma camera.
Participating Member States	Any country wishing to participate in this project

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Funding and project budget	<i>Provide an estimate of the total project costs and the funding expected from each stakeholder:</i>			
		Euro	Comment	
	<i>Government cost-sharing</i>	Approx. 7500 Euro	Including cost of investigations, I131 doses, admission and scan charges etc	
	<i>Counterpart institution(s)</i>			
	<i>Other partners</i>			
	<i>IAEA Technical Cooperation Fund (TCF):</i>	<i>Fellowships / Scientific visits / Training courses / Workshops</i>	Approx, 5500 Euro	workshops
		<i>Experts</i>		
		<i>Equipment</i>	Approx. 85000 Euro	for Thyrotropin alpha injections
	TOTAL	Approx. 98000 Euro		