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Design of Feasibility Study for the Establishment of 89Zr Production – Tailored Approach to Introduce New Radiopharmaceuticals in a Developing Country

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Establishing radiopharmaceutical production in a developing country is challenging, mainly in the economic aspect. A feasibility study provides an objective insight into many aspects of the feasibility of the idea of introducing new radiopharmaceutical. The feasibility study for establishing production of 89Zr is designed to include preliminary analysis, market research, technical feasibility analysis, economic analysis, review and analysis of all data, and feasibility conclusion. The preliminary analysis comprises a review of the application of 89Zrradiopharmaceuticals in clinical trials and a review of the cancer statistics on a national level. The technical feasibility determination is based on the analysis of the technical capacities of the production site – University Institute of Positron Emission Tomography. The economic feasibility estimation comprehends financial and pharmacoeconomic analysis, which aims to assess the justification for implementing a new radiopharmaceutical in clinical practice. For this purpose, a cost-effectiveness analysis is performed. 89Zr-trastuzumab is selected as a subject of the pharmacoeconomic estimation, based on the results of the preliminary analysis: 89Zr-trastuzumab is one of the most common 89Zr-radiopharmaceuticals in clinical trials, and on the national level the breast cancer is the most common malignancy and the most common cause of death from cancers in the female population.