# **Environmental and Social Data Sheet**

## Overview

Project Name:	MERCK PHARMA R&D II
Project Number:	2014-0559
Country:	GERMANY
Project Description:	R&D investments concerning the clinical development in the oncology and immunology during 2015 until 2018.

EIA required:

no

Project included in Carbon Footprint Exercise<sup>1</sup>: no

# Summary of Environmental and Social Assessment, including key issues and overall conclusion and recommendation

The project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. An Environmental Impact Assessment (EIA) is therefore not required by EIA Directive 2011/92/EU. The Promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry standards.

Considering the above, the project is acceptable for Bank financing.

## **Environmental and Social Assessment**

#### **Environmental Assessment**

As a group, Merck is ISO 14001 certified, meaning that all manufacturing sites are ISO 14001 certified. The R&D headquarters in Europe are also ISO 14001 certified.

Merck has a sound environmental policy including regular audits and reporting. R&D facilities and practices are in compliance with national and EU relevant regulation and the promoter maintains adequate internal procedures and management practices.

#### Social Assessment, where applicable

The clinical trials which are included in the project are performed under regulated and strictly controlled conditions, in existing specialised facilities which are regularly inspected by competent authorities - EMEA in Europe and/or national equivalent bodies in the rest of the World (FDA, PMDA, SFDA,..). The recruitment of patients is performed in accordance with the European directive (2001/20/EC) and/or equivalent international regulations in case of clinical trials performed outside Europe.

## **Other Environmental and Social Aspects**

Merck actively participates in associations and initiatives to promote scientific best practices and develop alternative research methods. With regards to animal testing, the promoter follows the guiding principles for more ethical use of animals in testing called Three Rs (3Rs). Replacement refers to the preferred use of non-animal methods over animal methods

<sup>&</sup>lt;sup>1</sup> Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO2e/year absolute (gross) or 20,000 tons CO2e/year relative (net) – both increases and savings.

whenever it is possible to achieve the same scientific aim: I) Replacement refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim, ii) Reduction refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals, and iii) Refinement refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used. It is fully in line with EU legislation (2010/63/EU).

Merck publishes a full Corporate Responsibility (CR) report every two years with annual updates, based on the guidelines of the Global Reporting Initiative (GRI). Since 2005, Merck participates in the UN Global Compact initiative, taking measures to implement ten principles on human rights, labour standards, environmental protection, and anti-corruption.