CIRT

CIRSE Registry for SIR-Spheres Therapy

Project Summary

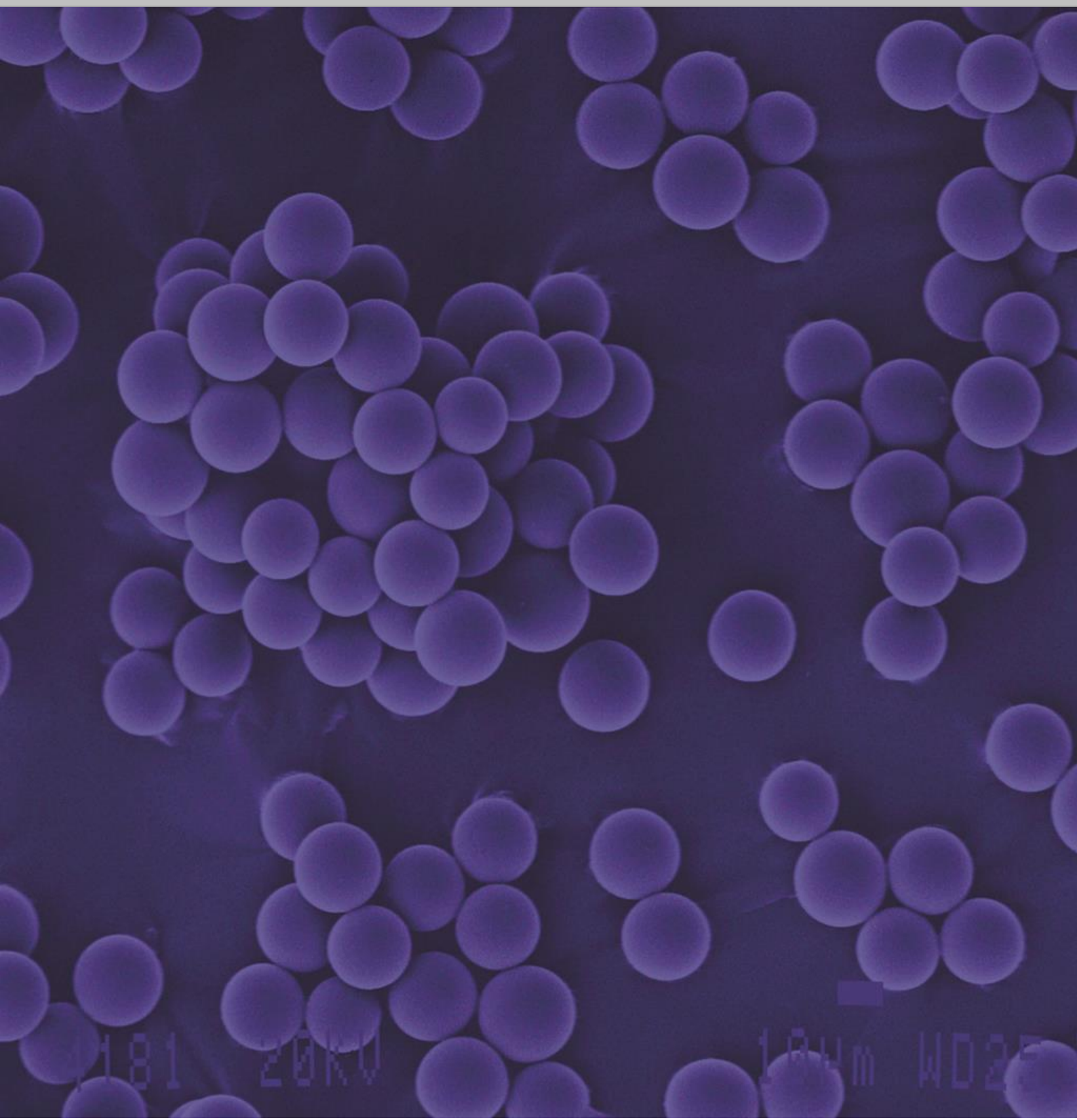
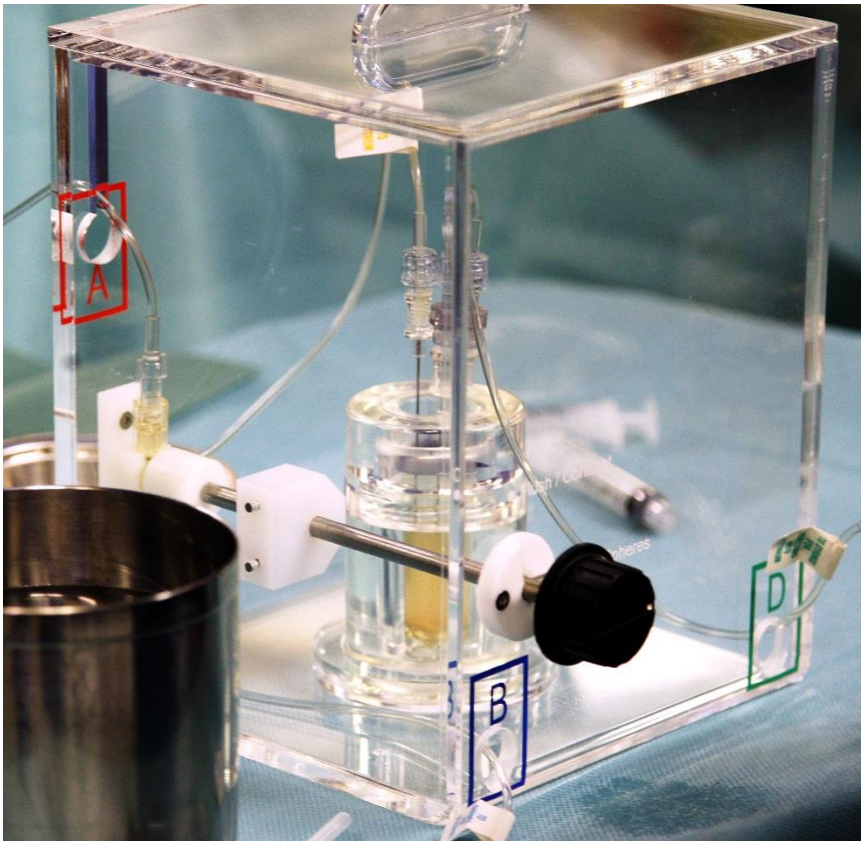


Table of Content



A complete vial with SIR-Spheres microspheres

1. Background

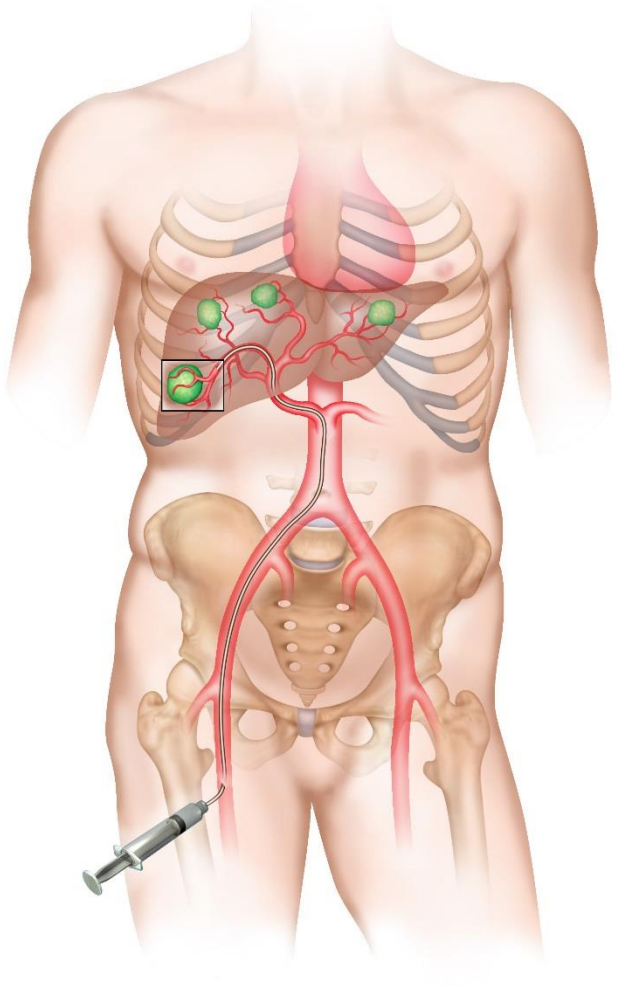
The administration of SIR-Spheres microspheres (yttrium-90 resin microspheres) is a form of selective internal radiation therapy (SIRT) for the treatment of patients with primary and secondary liver tumours. Previous reports on the safety and efficacy of yttrium-90 resin microspheres for the treatment of primary and secondary liver tumours are very promising.

In order to further improve our understanding of this therapy, CIRSE has initiated a European-wide observational study that enables data collection on the real-life clinical application of radioembolisation with SIR-Spheres microspheres. Furthermore, by including quality-of-life data and longitudinal follow-ups CIRT is sensitive to quality of life as an essential factor in liver cancer therapy.

2. Registry Objectives

The CIRT Registry has two major objectives:

- To collect robust data on the real-life clinical practice of radioembolisation with SIR-Spheres microspheres in a pan-European context.
- To collect data on the quality of life of patients treated with SIR-Spheres microspheres.



In radioembolisation, a catheter enters the bloodstream through the femoral artery and is advanced into the hepatic artery, where it releases radioactive particles directly into the affected region of the liver.

3. Methods

The registry is a prospective observational study that will enable data collection on SIR-Spheres therapy conducted by clinicians in registered centres. Besides data collection on the initial treatment, follow-up data will be collected depending on the clinical follow-up. To avoid including centres that are still in the learning curve of radioembolisation, it was decided that the registry will only recruit centres that can demonstrate a minimum level of expertise with SIR-Spheres therapy. This expertise is defined as a minimum of 10 cases in the last 12 months, and a minimum of 40 cases in total.

In order to meet the objectives of the registry, the CIRT Steering Committee developed an exhaustive list of data elements that will capture the diverse ways in which radioembolisation is performed throughout Europe. Additionally, CIRT will include a quality-of-life questionnaire to capture the change in quality of life of the patient before and after the procedure, and in additional follow-ups. For this registry, it was decided to use the QLQ-C30, a generic quality-of-life

questionnaire developed by the *European Organisation for Research and Treatment of Cancer* (EORTC) and that has been validated in various languages. In addition to the generic questionnaire, CIRT includes a module specifically designed for liver cancer patients: EORTC's QLQ-HCC Module.

4. Governance

The CIRT Registry is governed by three parties, whose responsibilities are complementary to each other and ensure that the study is executed according to the highest possible scientific standards: the CIRSE Society as the sponsor of CIRT; the CIRT Steering Committee as the scientific body; and the Principal Investigators at each site as the local Leadership. Figure 1 shows the governance structure in the form of a chart.

CIRSE

The registry is sponsored by The Cardiovascular and Interventional Radiological Society of Europe (CIRSE), a non-profit, educational and scientific association aiming to improve patient care through the support of teaching, science, research and clinical practice in the field of cardiovascular and interventional radiology. In CIRT, CIRSE has ownership of the data gathered by the registry, ensures that all data is collected anonymously, and provides all the technical requirements to guarantee data protection. The CIRSE Central Office will act as the "master administrator" and will facilitate communication between local hospitals and the CIRT Leadership.

Prof. José Ignacio Bilbao (Chairman of CIRT)

Steering Committee

The multidisciplinary Steering Committee will be primarily responsible for the scientific direction of the registry. The Safety Subcommittee and the Publication Subcommittee will oversee the patient safety and scientific output respectively. These (sub)committees consist of the following members:

Steering Committee/Publication Subcommittee

Experts	*Discipline*
Prof. José Ignacio Bilbao (Chairman)	IR
Dr. Roberto Cianni	IR
Prof. Thomas Helmberger	IR
Dr. Graham Munneke	IR
Dr. Jean Pierre Pelage	IR
Prof. Bora Peynircioglu	IR
Prof. Geert Maleux	IR
Dr. Bruno Sangro	Hepatology
Prof. Frank Kolligs	Internal Medicine
Prof. Derek Manas	Surgery
Dr. Samer Ezziddin	Nuclear Medicine
Prof. Niklaus Schäfer	Nuclear Medicine
Prof. Ricky Sharma	Oncology
Prof. Dirk Arnold	Oncology
Henk Tissing	Non-voting member from Sirtex

Safety Subcommittee

Prof. José Ignacio Bilbao (Chairman)
Dr. Roberto Cianni
Prof. Geert Maleux
Prof. Thomas Helmberger

CIRSE Central Office

Daniel Waigl (Chief Executive Officer)
Robert Bauer (Head of Department)
Niels de Jong (Clinical Data Manager)

Principle Investigators

At the local hospital level, the Principal Investigator (PI) is in charge of the CIRT Registry. The PI has the privilege of accessing the data from their hospital, suggesting publications to the Steering Committee, and enrolling subinvestigators within their own hospitals. In return, the PI will be responsible for the correct entering of data, including all consecutive patients treated with SIR-Spheres, and facilitating communication lines between CIRSE Central Office and the subinvestigators on site.

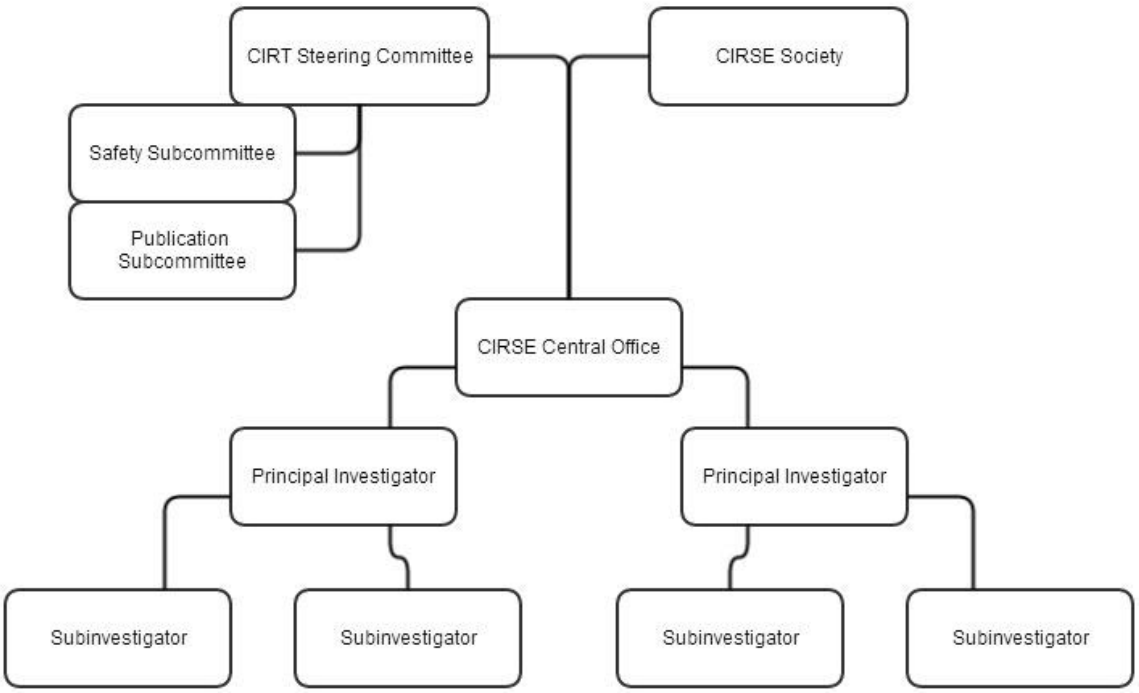


Figure 1: CIRT Governance Structure

5. Outcome

The registry aims to produce data on the real-life clinical use of SIR-Spheres in the treatment of patients with primary and secondary liver tumours and data on quality of life. This data can be used for the publication of peer-reviewed articles and to gather general information on SIR-Spheres therapy. CIRSE has the exclusive rights to the data and peer-reviewed articles.

6. Further Information

For more information on CIRT, please visit the website: www.cirse.org/cirt. If you have further questions please don't hesitate to contact Niels de Jong via dejong@cirse.org.