Scientific Societies Should Start Sponsoring Observational Studies

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In this editorial, we argue that scientific societies are in the ideal position to sponsor and conduct high-quality prospective observational studies and should actively take motions to realise this.

Should randomised controlled trials (RCTs) be considered the gold standard of medical research? While it cannot be denied that their rigorous methods are essential to show a therapy's inferiority, equality or superiority, interventional radiologists should not underestimate the value of other study designs when considering best practices. As the scientific discourse on evidence-based medicine has developed, so has the understanding that in the absence of well-designed randomised controlled research, observational study designs can offer evidence strong enough to inform clinical decision-making [1] as acknowledged in the Oxford Centre for Evidence Based Medicine [2]. In some situations, the randomisation of patients to multiple arms is unfeasible or unethical: rare diseases may not offer sufficient patient volumes for randomisation; the experimental drug may be the only available treatment option [3].

Considering the heterogeneous and dynamic field of interventional radiology, the very elaborate RCT design is not always able to keep up with new technological developments and clinical insights, which may reduce the usefulness of RCT results in the clinical reality. At the same time, interventional radiology needs large data sets and compelling evidence from paradigm shifting research, rather than small studies that result only in incremental improvements [4]. Observational studies can fill the void created by these practical limitations and address the low generalisability of RCTs—provided they are well-designed and controlled.

To that end, observational studies should be designed with the same rigour as RCTs: with clear outcome measures, well-defined inclusion and exclusion criteria, and precise follow-up periods. The high risk of selection and attrition bias must be acknowledged and accounted for in study design and results must be interpreted carefully, as they cannot establish if results

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are due to chance or a real effect as solidly as RCTs. If this is accomplished, observational studies can offer sufficiently strong evidence to base clinical decision-making on and even answer some important clinical questions that RCTs cannot.

Observational studies excel at generating real-world data that truly reflect clinical practice with the potential to confirm or refute randomised results and create new insights or hypotheses. Where randomised research is not available, observational studies can inform treatment guidelines and clinical practice due to their greater methodological flexibility and ability to collect high patient volumes. Registry study designs should therefore be conceptualised as synergistic. While RCTs are indispensable in comparing one therapy to another, observational studies are extremely important where this cannot be reasonably achieved or may not be the best option [5].

The EU seems to have acknowledged this signal with the new Medical Device Regulation (MDR 2017/745), which will be implemented next year. This new EU Regulation requires manufacturers to conduct post-market surveillance on all of their products to collect data on safety and performance (article 83, Annex III). With the approval and implementation of the new MDR, the EU sends a clear signal to medical device manufacturers and to the medical community that real-life observational data is essential in assessing the safety and effectiveness of medical devices. In this context, the MDR generates more demand for observational studies from the companies' point of view, which will lead to new opportunities for observational research projects and those able to conduct them.

Scientific societies are in a unique position, as they are membership-based organisations tailored towards education and dissemination of clinical information through congresses, education and workshops. In essence, scientific societies:

- Serve their membership, who need real-life data to make evidence-based medical decisions.
- Can operate independently from industry, thus creating a more robust data set that can better inform clinical practice.
- Have connections with both industry and physicians and can act as a broker between them, thus increasing the scientific credibility of the research output.

CIRSE picked up on this unique position and developed a research infrastructure intending to conduct high-quality observational research. CIRSE's dedication to the development and implementation of research in cardiovascular and interventional radiology is reflected in its research principles:

1. *Produce high-quality clinical data* by identifying and closing gaps in clinical knowledge by using rigorous pre-defined objectives and methodologies.
2. *Conduct independent research* with grants provided by industry to generate scientific data that can be published in peer-reviewed journals and used for reimbursement or regulatory purposes.
3. *Conduct research in an efficient and cost-effective manner* with dedicated staff and standard operating procedures, taking advantage of society synergies to save costs and maximise the impact of the study results.
4. *Provide a valuable service to our members and the medical community* by being investigator-driven, service-oriented and tailoring research projects to the needs of the medical community.

Well-designed observational studies are excellent sources for evidence-based clinical practice and can complement data from RCTs. Scientific societies are at the crossroad between physicians, industry and healthcare regulators and are in the perfect position to generate high-quality observational data independent from industry influences. The current regulatory climate is ideal for scientific societies to position themselves as a credible party which can fulfil the needs of its members, their industry partners and the European regulators. To address these needs, CIRSE has embarked on the task of setting up the following observational studies: CIRSE Registry for SIR-Spheres Therapy (CIRT), the CIRSE Registry for LifePearl Microspheres (CIREL), the CIRSE Registry for SIR-Spheres Therapy in France (CIRT-FR) (whose first results were presented at the CIRSE 2020 Summit)—and the newest addition, the CIRSE Registry for EMPRINT Microwave Ablation (CIEMAR); the CIRSE policy of independent, investigator-driven observational studies funded by unconditional research grants from industry partners has shown to be effective in paving the way to a new era of society-sponsored clinical research.

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Compliance with Ethical Standards

Conflict of interest The authors declare no conflicts of interest

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