**RESULTS:**

Accessing RWD from registries proved difficult due to multiple reasons, including: complex and non-transparent application procedures, resistance from registry owners to discuss applications and datasets not being research-ready within project timeframes. There were also issues with the RWD eventually accessed, including a lack of individual participant data (IPD) and incomplete data. Where access to IPD from RCTs was obtainable, there were restrictions imposed on how it could be used. For example, it could not be used to target analysis on an individual product, but rather explore methodologies for data synthesis in a product-anonymised setting. This condition encouraged additional data sharing by other stakeholders.

**CONCLUSIONS:**

Despite the collaborative, multi-stakeholder nature of IMI-GetReal and proper disclosures with data owners, access to data proved challenging. Such barriers to data accessibility can delay effectiveness research, restrict opportunities for the development of methods incorporating RWD and diminish the potential use of RWD in decision making. Where data is intended to be used for this purpose, sufficient attention should be paid to these potential barriers.

## VP116 Comparison Between Time To Off Treatment And Italian Medicines Agency Registries Treatment Duration

**AUTHORS:**

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**INTRODUCTION:**

The Italian Medicines Agency Registry represents a tool that could be a precious source of information regarding the mean treatment duration of a drug in a real world context. Monitoring registries are applied at the national level after market authorization and are designed not only to apply the Managed Entry Agreements (MEAs) but also to collect Real World Data on drugs safety, effectiveness and real life utilization. The purpose of this analysis was to compare the treatment duration from clinical trials and the mean treatment duration calculated using data from monitoring registries (1).

**METHODS:**

For each drug included in the analysis it was collected the treatment duration from Time To Off Treatment curves for the experimental drug (eTTOT) from Phase III clinical trials and the mean treatment duration data calculated by using the number of cycles (converted in months of treatment) of all treated patients extracted from AIFA registries (TTAR). The mean ratios between the Time of Treatment of Italian Medicines Agency and Experimental arm time to off treatment were calculated to identify potential correlations. High level of correlation was expected if Time to Payment By Result /Time To Off Treatment ratio was close to 1 (±.2).

**RESULTS:**

Six Roche products or different indications of the same product were identified as candidates for the analysis from 2013 to 2016. The mean TTAR/eTTOT ratio observed in patients treated from 2013 to 2016 was .97 (±.10), meaning that the mean treatment duration calculated from AIFA Registries is strongly comparable with the treatment duration observed in clinical trials. In one case the TTAR is even more major than eTTOT.

**CONCLUSIONS:**

A high level of correlation between TTAR and eTTOT was found. Additional analyses considering different cohorts of patients over time could be useful to have a more precise estimate of real world drug utilization. Even though RCTs remain the gold standard for demonstrating clinical efficacy in restricted trial setting, Real World Evidence from AIFA registries can contribute to the evidence base needed for healthcare decisions.



https://doi.org/10.1017/S0266462317003737 Published online by Cambridge University Press

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## VP120 A United Kingdom Research Commissioning Framework For Devices And Diagnostics

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**INTRODUCTION:**

Generation of high-quality evidence on medical devices through clinical trials can be challenging. The United Kingdom's National Institute for Health and Care Excellence (NICE) has developed a research commissioning framework for producing clinical evidence where gaps in the literature prevent definitive recommendations in their medical technology guidance and diagnostics guidance. The research commissioning framework involves NICE's external assessment centers collaborating with clinical researchers to secure funding and to design, conduct, and publish a study to address research recommendations within 3 years of guidance publications. We aimed to describe the early results of the framework.

**METHODS:**

Publically available information and results from an informal survey of NICE's external assessment centers were reviewed.

**RESULTS:**

As of December 2016, NICE has published a total of thirty medical technology guidance topics and twenty-four diagnostics guidance topics, five and twenty of which have research recommendations, respectively. A total of fourteen research commissioning framework-facilitated projects have been initiated. Two research projects have successfully secured external funding for a clinical trial: (i) non-contact low frequency ultrasound therapy for wound healing; and (ii) Parafricta bootees for pressure ulcer prevention. Further projects have produced published outputs without external funding. Four projects have been completed and undergone guidance review; one guidance topic was withdrawn and three have been transferred to the "static list". Early experiences of NICE's research commissioning framework suggest that securing financial support from manufacturers or funding bodies for interventional clinical trials to answer single technology research questions within a short time frame is challenging but possible. The value of early feasibility studies to assess the likelihood of obtaining funding and of addressing NICE's research recommendations was recognised.

**CONCLUSIONS:**

NICE can facilitate independent research through its research commissioning framework initiative. Securing funding has proved challenging but recent successes have shown that approach is possible. Outputs which fill the evidence gap to an extent where a definitive guidance update is possible have been rare.

## VP122 Cryoballoon Versus Radiofrequency Ablation For Atrial Fibrillation

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**INTRODUCTION:**

Pulmonary vein isolation (PVI) is a new effective treatment for atrial fibrillation (AF) (1). The standard of care for ablation methods using radiofrequency (RF) is time-consuming and technically challenging (2), and restricted to a few specialized centers, which causes the limited availability of ablation therapy (3). Therefore, cryoballoon (CB) ablation has been developed to



https://doi.org/10.1017/S0266462317003737 Published online by Cambridge University Press