

The Challenges and Benefits of Large-Scale Multi-Country Monitoring Studies

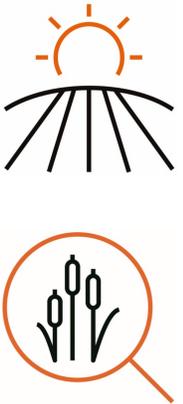
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Abstract

Increasingly, regulatory authorities across Europe are requesting higher tier monitoring to refine modelling outcomes and / or to provide real-world data on the environmental fate of plant protection products (PPP) for registration purposes. Higher tier groundwater monitoring studies offer well documented advantages over reliance on mathematical modelling approaches, however the costs of undertaking such studies individually across several geographies, for different national regulators, using different approaches, can be prohibitive and challenging to manage. As such, a number of registrants have commissioned single, multi-country studies to increase efficiencies and provide large-scale and robust data sets.

Over the past decade Arcadis has undertaken numerous multi-country groundwater monitoring studies on behalf of several PPP registrants. Below, we present details of the challenges and benefits encountered by Arcadis in undertaking large-scale multi-country groundwater monitoring studies and provide insights into the methods used to ensure the studies are fit for purpose.

The primary challenges and benefits encountered can broadly be categorised into 3 main areas: implementation and delivery of the studies; interpretation of the study data; and acceptance by regulatory bodies. Each of these areas is discussed in detail, including the overall impact to the study, as well as in terms of learnings for the conduct of future studies.



Implementation & Delivery

Challenges:

Logistics; The need to mobilize large teams and equipment across several geographies, the availability of consistent materials & consumables.

Consistency of Procedure; the need to standardize the methodology used and ensure this is followed by team members in different countries, such that the data produced is comparable.

Choosing Locations; care must be taken to ensure that suitable areas are selected for the study, e.g., Focus zones, areas of higher leaching vulnerability, and pressure of use such that the needs of the study / regulators are met. Furthermore, sufficient monitoring locations in each Focus zone or geography should be included.

Consistency of Data; different geographies will often have different approaches / levels of maturity associated with e.g. PPP usage records, agricultural practices, how open farmers are to participating in studies of this nature.

Benefits:

Robust Approach; The implementation of a robust and consistent approach to implementation and delivery across the study ensures that the data collected is of high quality and provides a high-quality output.

Cost Efficiency; Delivering a large-scale study across multiple geographies provides significant cost savings compared with completing individual studies for each separate country, from a logistical, technical and GLP point of view.

Specialised Team; As the project will be delivered by a focused and specific team, this allows for learnings and best practice to be carried through the entire project.

Future Use; Having a study with monitoring locations spread across a variety of countries / geographies / Focus zones / cropping will potentially allow for follow on studies, on other PPPs, to be easily undertaken using some or all of these locations depending on need.



Figure A: Monitoring Sites for a Multi-Country Study

Interpretation of Study Data

Challenges:

Consistency; As the study data will be collected across different geographies, there will be differences in geological, hydrogeological and climatic conditions. In addition, the farming practices and usage of the PPP in question are also likely to be variable. As such, care is needed in interpretation of results such that these differences do not skew the overall outcome of the study

Benefits:

Consistency of Data; As the data will be collected to a consistent standard across the study, the data will therefore be comparable and provide a large set of high-quality data. In turn, this will allow for in-depth analysis and formulation of detailed conclusions, the identification of outlying data / sites, and determination of the relative effects of different site conditions and PPP usage approaches.

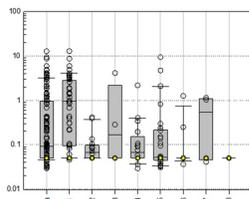


Figure B: Distribution of Residue Results by Stratum Across a Single Multi-Site Study

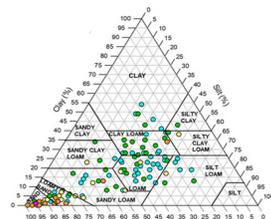


Figure C: Groundwater Residues and Surface Soil Texture Across Multi-Site Study



Figure D: Hydrogeological Vulnerability Map

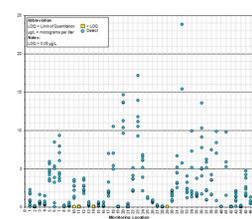


Figure E: Groundwater Residue Results Across Multi-Site Study

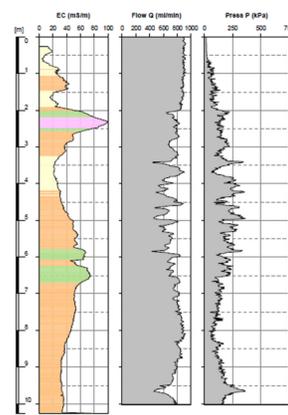


Figure F: Results from a Hydraulic Profiling Tool

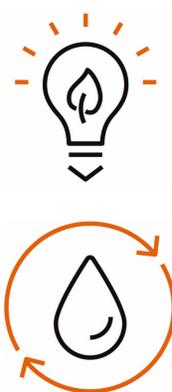
Acceptance by Regulatory Bodies

Challenges:

Local country requirements; A multi-country study will face the challenge of meeting each of the local, in-country regulatory requirements, as well as any European level stipulations, in order to gain acceptance across the remit of the study.

In-country Review; Once complete, the study may be reviewed on a local scale, as well as national and continental. Regulatory bodies in different geographies will often have different levels of maturity / approaches to review and perception of environmental risk, and hence are likely to have differing opinions on the same data.

Regulatory changes during study; Changes to the regulatory requirements, national guidance or best practice for the conduct of such studies which occur during the conduct of a study can provide challenges to any study. This risk is heightened in situations where the study is being undertaken across multiple geographies.



Benefits:

Consistency; The robust and consistent methodology required to complete a multi-country study will provide data that is much easier for a regulatory body to understand and evaluate.

Comparability; Having a large-scale study that has been conducted across multiple geographies, taking account of the current guidance & best practice from each of the countries, will give greater confidence to individual regulatory bodies that the study has been designed and conducted appropriately.

Multiple Acceptance; Through the course of the study, results / interim reports may be shared with particular regulatory bodies. The knowledge that other local or national regulatory bodies are comfortable with results may help the overall acceptance of the study.

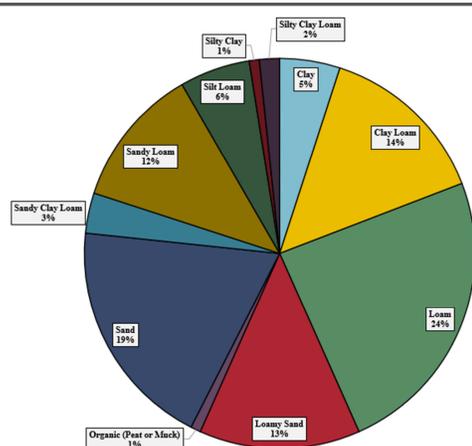


Figure G: Distribution of Soil Textures Across Large-Scale Monitoring Program

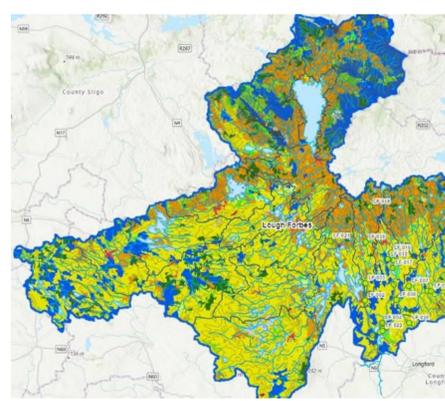


Figure H: Catchment Level Monitoring Locations with Soil Textures

CONCLUSIONS

- Conducting large-scale multi-country studies involves a number of challenges both from a **logistical** and **technical** perspective.
- The **benefits** of such studies can be **significant**, however **suitable planning** is needed.
- The data generated by these studies is **highly valuable** but **care must be taken** in the **interpretation** of the results to obtain **greater value** from the study.
- **Regulatory acceptance** can be improved using large-scale data sets from **multiple geographies** however it is important to account for **local requirements, guidance and best practice**, where relevant.