

CRO in the EU North Zone within field research and regulatory consulting



Independent
**Regulatory Consulting
& Field Research**



Regulatory consulting in plant protection product and fertilizing product registration. Service provider in field trials GEP, GLP, 1107, FPR, biocides, Variety testing and various other trials.

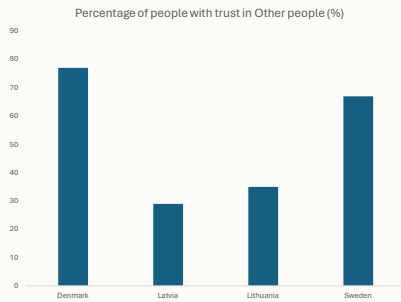


From a regulatory field trial perspective

Corporation in EU North

Owned or operated Field Stations in Denmark, Sweden, Latvia & Lithuania ●
Collaboration with other CROs in Finland, Estonia and Norway ▲





Trust

Culture and communication

Priorities and expectations

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Trust is a major barrier when it comes to cross border and cross discipline corporation, especially true for the CRO industry. Also for working between cultures.

Going outside the Nordics to EU or the world key challenges and priorities change. Challenges and opportunities. Africa and microorganism based products.



Hofstede's Cultural Dimensions



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Six categories that define culture

Cross border corporation



Regulatory Environment: Plant Protection Product regulation (1107), FPR and biocides, member state specific



Calibration: Accreditation and certification – Member state authorities.



EU wide **harmonized and standardized** field trial methods.



Common EU **field trial language and data management tool** used by industry, CRO/CRAO and authority.



Standard Operating Procedure uniform approach across all partners.



Regional differences in cropping systems, good agricultural practice, farmer methods, legislation, field trial knowledge

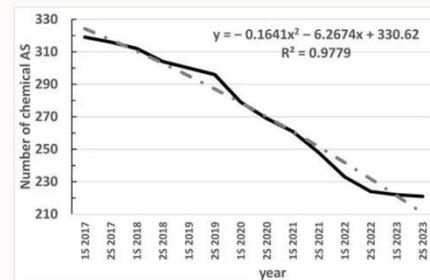
Partnerships



Barriers for testing biocontrol and biostimulant products:
Field trial costs
Regulatory barriers

Exploring low-cost field trial technology – standardized, scalable and regulatory compatible

Plant production chemical and biosolution toolbox is changing, so is field trial requirements (MOA).



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AI are disappearing, no funding available for developing new. Biocontrol and biosolutions plays a role in taking over. Costs for product development, testing and launch are the same, end still the efficacy and consistence gap is and issue. Quality vs. quantity.
Flexibility and adaptability – 40 years of experience adapting to trials on the market



Creating value

Maintaining high trial success rate for novel biosolution and biocontrol products. Balancing trial costs and quantity.