

“Forward together – but stay on the road” (WP-3 Evaluation)



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WP 3 - Evaluation

- ⇒ **On 1 June 2013, the Health and Social Care Inspectorate (IVO)** was created as a new government agency that is responsible for supervising health and medical care, social services and services under the Act concerning Support and Service for persons with Certain Functional impairments as well as considering permits to a certain extent.
- ⇒ National Board of Health and Welfare remains as the regulatory agency.

Quick facts about IVO

- **The Ministry of Health and Social affairs is responsible for the Health and Social Care Inspectorate**
- **IVO's operations are funded by grants with an annual budget of approximately SEK 650 million**
- **IVO has around 550 employees**
- **IVO operates at six regional offices across Sweden and three cross-agency departments in Stockholm.**

- **One unit in Stockholm is responsible for National supervision and National coordination of Blood and Tissues & Cells , as well as authorizing the establishments according to the EU-Directives.**

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National supervision and coordination

- **Inspections of all (52 / 79) Tissue Establishments in Sweden**
 - Hematopoietic stem cells (living donors)
 - Gametes (ART-clinics) - living donors and healthy recipients
 - Skin , Bone (living and deceased donors)
 - Cornea, heart valves, liver cells, insulin producing cells, ... (deceased donors)
- **Coordinate**
 - collect and evaluate all reported Severe Adverse Effects and Severe Adverse Reactions
 - Provide guidance on legal and technical aspects to the Tissue Establishments
 - The Competent Authority / contact point to and from EU-COM
 - Analyze our observations and produce reports and meetings for dialogue with the tissue establishments and the public

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Why and how is IVO going to evaluate the ARTHIQS ?



Internal experts: in ART, HSC and legal issues

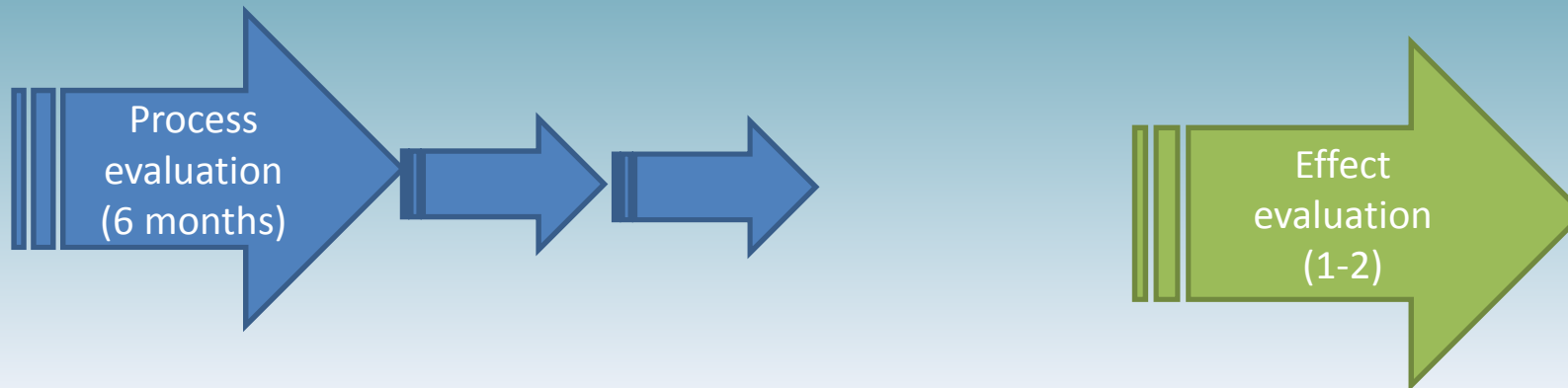
External experts: (NGO)



SALAR represents the governmental, professional and employer related interests of Sweden's municipalities, county councils and regions

The National Tissue Council; committees for each tissue / cell type consisting of professional expertise for each tissue.

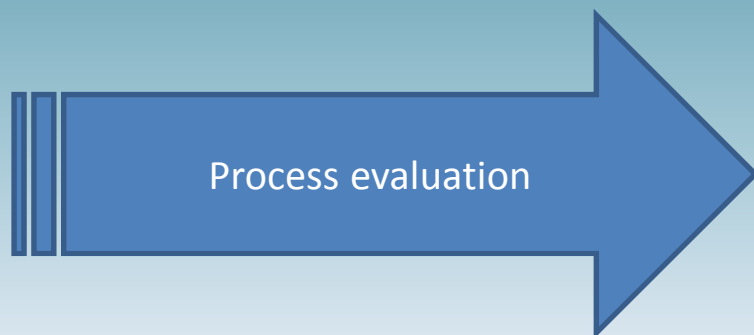
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- **Does the ARTHIQS project proceed as planned ?**

- **Does the ARTHIQS project achieve its goals ?**

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- **Planned meetings – completed ?**
- **Guidelines – draft – sent for consultations ?**
- **Survey(s) sent to EU member states ?**

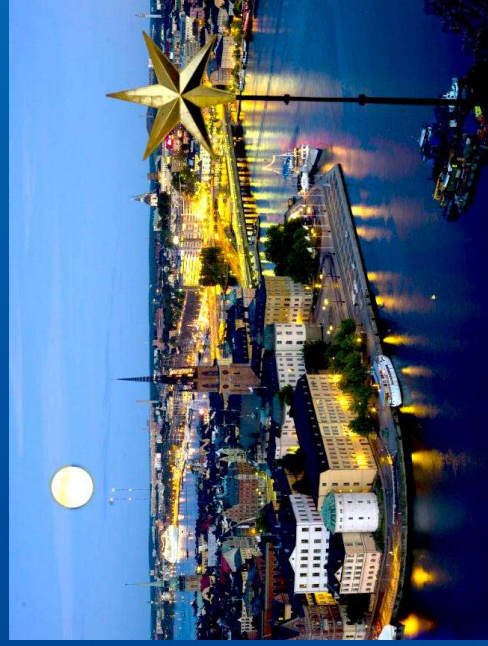
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Effect evaluation

- **Response rate to Surveys – 75 %**
- **Response rate to the training guidance – 75 %**
- **ART- Guidelines for inspections finalized**
- **HSC guidelines for Donor follow up registry finalized**
- **Cord Blood Banking guidelines for inspections finalized**
- **MS awareness / usefulness ? -Survey at the end of ARTHIQS**

THANK YOU



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