

THE RIGHT TO OPT OUT IN THE EHDS REGULATION AS A RISK AND A SAFEGUARD

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The right to opt-out in the EHDS regulation

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graph TD; A[The right to opt-out in the EHDS regulation] --> B[In primary use]; A --> C[In secondary use];
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In primary use

In secondary use

The right to opt-out in primary use

- Fewer data subjects
- Usually not de-identified
- Data user (e.g. physician) usually knows the patient personally

The right to opt-out in secondary use

- More data subjects
- Data is anonymized/pseudonymized
- Data user (e.g. researcher) does not know the patient personally

The right to opt-out as a risk

- Identification before erasure
- Each Member State should establish their own rules and safeguards
- Opt-outs do not propagate automatically across borders
- Opt-out registry (TEHDAS2 suggestion)
- Reversibility of opting-out
- Different type of patients

The right to opt-out as a safeguard

- Comprehensive opt-out system
- No justification needed for exercising the right to opt-out

Thank you for your attention!

Further questions/comments?
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