EU CanScreen
European Joint Action on Cancer Screening

T5.1 Ethical, Legal and Social Implications (ELSI) assessment of data sharing

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T5.1 at a glance

Assessing the ethical, legal and social implications of sharing cancer screening data across Europe

Aim

Identify what enables and what limits responsible sharing of screening data, and turn it into practical guidance and digital tools.

Three levels

- Individual (participant / patient)
- Institutional
- Societal

Impact of AI assessed across all three

Outputs

- **MS25: ELSI legislation (M24, submitted May 2026)**
- D5.2: ELSI assessment report (M36)
- Optional: systematic review (M36)

Team

- Lead: DYPEDE (Greece)
- 10 partner institutions
- Subcontracted legal review on ELSI

Where ELSI comes from

Born with genomics: the idea that science should study its own consequences while it is being done

1

1988–1990

Human Genome Project

In the US, the NIH (3%, later 5%, of its genome budget) and the DOE fund research on ethical, legal and social implications: the first ELSI programmes.

2

1990s

ELSA in Europe

EU framework programmes fund research on Ethical, Legal and Social Aspects (ELSA) of the life sciences.

3

2010s

Responsible Research and Innovation

Horizon 2020 broadens ELSA into RRI: public engagement, ethics, open access, gender and science education.

4

Today

Data, AI and digital health

ELSI is applied to big data, artificial intelligence, biobanks and cross-border health-data sharing.

Core idea: ELSI work runs alongside the science, not after it, so that its findings can shape policy, practice and technology design.

Sources: [2–4]

Theoretical frameworks for ELSI assessment

Principlism

Beauchamp & Childress

- **Respect for autonomy**
- **Beneficence**
- **Non-maleficence**
- **Justice**

The shared language of biomedical ethics; the basis for most consent and data-protection rules.

Responsible Research and Innovation

AREA framework

- Anticipate impacts
- Reflect on purposes and assumptions
- Engage stakeholders and the public
- Act on what is learned

Makes ELSI a continuous process built into the project.

Embedded and participatory ELSI

"ELSI by design"

- ELSI researchers work inside the project
- Upstream: before choices are locked in
- Citizens and patients co-design the rules
- Evidence feeds directly into governance

The model T5.1 follows: ELSI assessed with the partners, during the project.

Sources: [4–6]

Key ELSI concepts for health-data sharing

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Right to benefit from science

Article 27 of the Universal Declaration of Human Rights underpins the GA4GH Framework for Responsible Sharing of Genomic and Health-Related Data (2014).

Consent models

Specific, broad and dynamic consent, plus opt-out and legal bases other than consent (e.g. public interest in public health).

Privacy and re-identification

Pseudonymised data remain personal data; genomic data can identify a person and their relatives.

Public interest and solidarity

Sharing justified by benefits to the population, balanced against individual rights.

Trust and trustworthiness

Transparent governance, accountability and public engagement earn the trust that sharing depends on.

FAIR and secure data

Findable, accessible, interoperable and re-usable data, accessed in secure environments.

Sources: [8–11, 13]

Why sharing screening data matters

1. **Bigger, more representative evidence.** Pooling data increases study size for less common cancers and subgroups, allows datasets to be examined from new angles, and captures differences between populations and regions.

2. **Better programmes.** Shared data let screening programmes compare quality indicators, performance and outcomes across countries.

3. **Participants expect it.** People often take part in screening and research to help others like themselves, and they have expectations about how their data will be shared.

4. **Institutions decide the value.** The ultimate contribution of their data depends on the institutions that store and govern it.

5. **The gap today.** Data sharing is still limited and is one of the main barriers to cancer research. Participants are disheartened when they learn their data have not been used effectively.

Sources: [8]

Genomic data raise the stakes

- Precision cancer medicine and risk-based screening rely on access to, use of and exchange of genomic and associated clinical data.
- The ELSI of this access, use and exchange are accentuated in cancer because genomic data are highly sensitive, reveal information about relatives, and carry uncertain risks of re-identification.
- Systematic analyses of why and how next-generation sequencing (NGS) data may be shared responsibly are, however, limited.

What this gives institutions

A complete list of ELSI reasons and conditions for responsible sharing: an evidence base for data-sharing policies.

Institutions should encourage sharing of cancer data to advance research, while using re-consent and data-protection mechanisms that reduce uncertain long-term risks to patients and their families.

Sources: [12]

How ethics, law and society interact

- Ethics (E) is the norm society depends on: it changes over the long term but is stable in the short term, and it should be the basis of law (L).
- Law must be reviewed constantly against ethics, but it is also shaped by society (S), and public opinion can be volatile.
- Emerging technologies may not fit existing laws or may require new ethical norms. The arrival of cameras in the late 19th century led to the concept of privacy rights. Cheap drones exposed gaps in aviation law.
- Social acceptance is essential: if society rejects a technology, even a lawful one carries reputational risk.
- Innovation therefore requires E, L and S to be updated together.

In cancer screening today

- AI-supported reading of mammograms and other images
- Risk-based invitations using polygenic or other risk scores
- Genomic and biomarker tests in screening pathways
- Pooling registry, imaging and genomic data across borders

Each moves faster than the rules and norms that govern it.

Three levels of the ELSI assessment

1 Individual

participant / patient

Informed consent and respect for preferences, especially with NGS, which can yield many different types of genetic information, including incidental findings.

2 Institutional

stakeholders

Professional organisations in genetics and oncology, test laboratories, clinical trial networks and screening programmes deciding which results to analyse and return to patients or research participants, and how to manage the clinical implications.

3 Societal

policy

Resource allocation, priority setting and equitable access to screening and to the benefits of shared data.

Cross-cutting: the impact of artificial intelligence is assessed at all three levels.

Sources: [1]

Artificial intelligence across the three levels

Individual

- Transparency that AI is used in reading or risk scoring
- Consent for use of screening data to train or validate AI
- Access to human review of AI-supported decisions

Institutional

- Validation and ongoing monitoring of performance
- Accountability when AI misses or over-calls a cancer
- Compliance with EU rules for high-risk medical AI

Societal

- Equal performance across populations and settings
- Bias from under-represented groups in training data
- Public trust and the role of the professional

Issues to be examined in T5.1, not results.

Sources: [16]

Ethical issues

Core principles for sharing screening data

Autonomy: informed, broad or dynamic consent; the right to withdraw

Beneficence: the benefits of sharing should outweigh the risks

Non-maleficence: minimise harm, including re-identification and distress from unexpected results

Justice: fair distribution of benefits and burdens, including for under-represented groups

Return of results: what to return, to whom and how, especially for genetic findings

Three ethical lenses (Zack 2009)

Consequentialism: judges actions by their outcomes for people

Deontology (duty ethics): follows moral principles regardless of the specific outcome

Virtue ethics: rests on character and shared values

Using all three lenses helps balance individual rights against public-health benefit.

Sources: [5, 7, 10]

Legal issues

Lawful basis

Health and genetic data are special categories under the GDPR (Art. 9). Research use needs a legal basis and safeguards (Art. 89).

National variation

Rules on secondary use, consent and ethics approval differ between Member States, so sharing is uneven.

Cross-border sharing

Data-sharing agreements must define controllers and processors, responsibilities and liability.

Anonymisation

Anonymised data fall outside the GDPR, but genomic data are difficult to anonymise fully.

Results and liability

Duties to return results and incidental findings, and the liability that follows, vary by country.

Access and ownership

Who may access, re-use and benefit from the data, and under what conditions.

Sources: [13, 17]

EU legal and policy framework

Instrument	Reference	Relevance to screening data sharing
General Data Protection Regulation (GDPR)	Regulation (EU) 2016/679	Legal basis and safeguards for processing health and genetic data
Data Governance Act	Regulation (EU) 2022/868	Trusted re-use of protected public-sector data; data altruism
Council Recommendation on cancer screening	2022/C 473/01	Updated EU screening recommendations; monitoring and evaluation of programmes
Artificial Intelligence Act	Regulation (EU) 2024/1689	Risk-based rules; AI in medical devices generally treated as high-risk
European Health Data Space (EHDS)	Regulation (EU) 2025/327	Framework for primary and secondary use of health data through health data access bodies; secondary-use rules apply mainly from March 2029

MS25 mapped the national legislation that applies alongside these instruments in the 29 EUCanScreen countries.

Sources: [13–17]

Social issues

Ethics asks whether sharing is morally acceptable; the social dimension asks whether society accepts it.

Trust

Willingness to share depends on trust in institutions and transparency about who uses the data and why.

Equity

Under-represented groups in datasets lead to biased tools and unequal benefit.

Stigma and discrimination

Genetic and risk data could affect insurance, employment or family relationships.

Engagement

Citizens, patient organisations and health professionals should help shape the rules.

Digital divide

Digital consent and results tools must not exclude people with low digital or health literacy.

New vulnerabilities

Technology can strengthen screening but can also create new risks, such as data breaches.

Sources: [8, 12]

Protocol to measure ELSI (1/2)

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1. **Define the scope**
   Screening programme(s), data types (registry, imaging, genomic), stakeholders, country and cultural context.

2. **Identify ELSI issues**
   Literature and systematic review; consult experts in ethics, law and social sciences; collect national legislation (MS25).

3. **Develop research questions**
   Specific, relevant, feasible and answerable questions for each identified issue.

4. **Select methods**
   Qualitative (interviews, focus groups) and quantitative (surveys, document analysis) to capture all stakeholders.

5. **Obtain ethical approval**
   Ethics committee review; compliance with the GDPR and national rules.

Protocol to measure ELSI (2/2)

6 **Collect data**
Recruit participants at individual, institutional and societal level; protect confidentiality and well-being.

7 **Analyse and interpret**
Relate findings to the research questions and the wider ELSI context.

8 **Disseminate**
Share with stakeholders, policymakers and the public; publish in peer-reviewed journals; present at conferences.

9 **Recommend and implement**
Develop recommendations and work with screening programmes to apply them.

10 **Monitor and evaluate**
Follow up implementation and adjust as needed.

The T5.1 toolbox: seven tools

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Evidence	Expert and stakeholder input	Assessment	Output
1 Systematic review	4 Legal review	6 ELSI assessment framework	7 Digital tools
2 Partner survey	5 Stakeholder engagement		D5.2 report (M36)
3 National legislation			

Each level (individual, institutional, societal) is covered by every stage, so the final tools rest on evidence, law and stakeholder views together. Tools 2 and 3 (pink) were delivered through MS25 in May 2026.

Tool 1 · Systematic review of reasons

1 *What reasons, and what conditions, does the literature give for responsible sharing of cancer genomic and clinical data?*

Output: M36

How it works

- Structured search of the bibliographic literature
- Screening against predefined inclusion criteria
- Extraction of ethical, legal, social and scientific reasons, and the conditions attached
- Synthesis into ELSI categories at each level

Method: systematic review of reasons (Strech & Sofaer 2012).

Across the three levels

Individual: consent, re-consent, return of results

Institutional: data-sharing policies and governance

Societal: public benefit, equity, trust

Output

Evidence base for D5.2 and an optional peer-reviewed publication (M36)

Sources: [12, 18]

Tool 2 · Partner survey (MS25)

Milestone 25 (M24) submitted on 29 May 2026: the first summary of ELSI requirements for sharing cancer screening data

39
completed questionnaires

28
participating countries: all of EUCanScreen

10
Spanish regions responded

The survey

- Led by CPO with DYPEDE and NIPH, 2025/2026
- Data last updated on 12 May 2026
- Its legal section is the basis of MS25 and of D5.2
- Methods and the other sections are reported in MS26
- Some countries sent more than one response (Spain: 10 regions; Belgium: 2)

Questions at three levels

Societal: legislation behind screening programmes, and what it allows or limits, including registry linkage

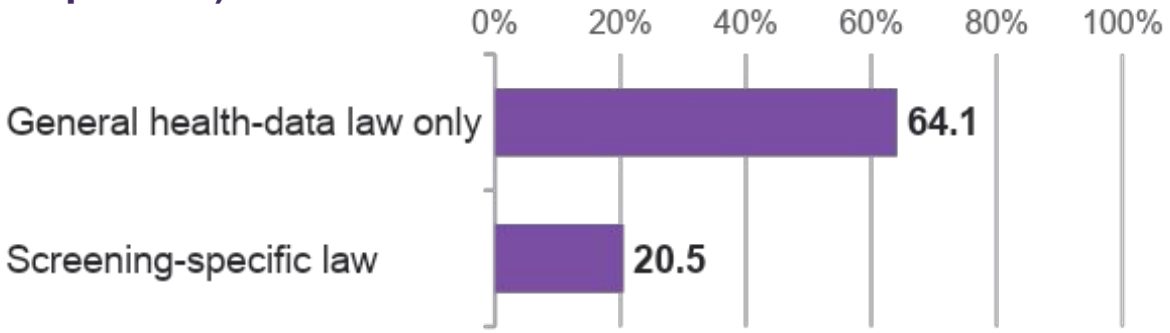
Institutional: returning sequencing results to patients

Individual: consent models, including dynamic consent, where consent is the legal basis

Sources: [1]

Societal level: legislation and registry linkage

Legislation on screening data, beyond the GDPR (% of responses)



Individual-level linkage legally permitted (% of responses)



Who reported what

Screening-specific legislation

One Belgian region, Czechia, Ireland, Moldova, Norway, Slovenia, 2 Spanish regions

Restrictions on linkage with cancer registry

Cyprus, Greece, France, Hungary, Poland, 2 Spanish regions

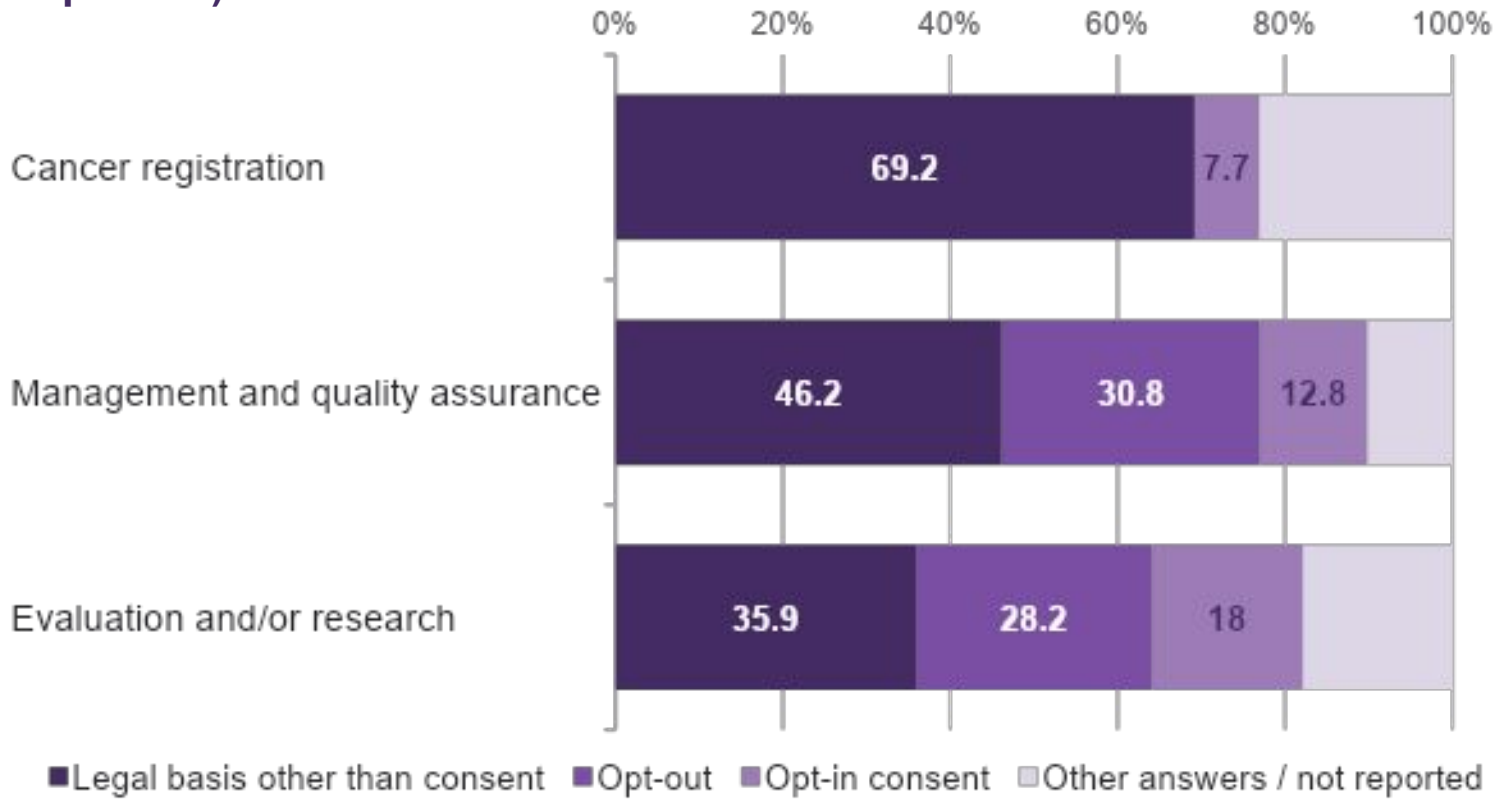
Restrictions on linkage with cause-of-death registry

Belgium, Germany, Greece, Croatia, Hungary, Ireland, Italy, Latvia, Moldova, Poland, Portugal, Romania, 1 Spanish region

Sources: [1]

Individual level: legal basis and consent

Legal basis for processing identifiable screening data, by purpose (% of responses)



Percentages as reported in MS25; the remainder is shown as other answers or not reported.

Consent becomes more common for research

Opt-in for research: Hungary, Ireland, Moldova, Poland, Romania, Sweden and 1 Spanish region.

Dynamic consent

No country that relies on consent uses electronic dynamic consent yet. Ireland and Romania are developing a solution.

Sources: [1]

Institutional level: genetic data

84.6%

of responses reported no use of genetic data in screening programmes

Returning sequencing results is not yet an issue for most programmes. It will become one as risk-based screening grows.

What respondents told us

Ireland: the National Screening Service does not hold, or intend to hold, genetic data, so no procedure exists.

Spain (Basque Country): informed consent is mandatory when a project involves AI, genetic data or biobanks.

Ukraine: risk-based prostate screening often involves genetic testing. The law on human genomic information and the Oviedo Convention are relevant.

Implication for D5.2: prepare rules on consent and return of results before genetic and risk-based screening scales up.

Sources: [1]

Tool 3 · Collection of national legislation

3 *Which national laws, beyond the GDPR, govern screening data in each country?*

Delivered

How it works

- Survey respondents cited the domestic legislation that applies and commented on how it works
- Texts and links compiled in MS25 Annex 1
- Used to interpret the survey answers and to identify gaps and unclear rules

Across the three levels

Societal: legislation behind programmes; linkage with cancer and cause-of-death registries

Institutional: rules for genetic data in screening

Individual: legal basis for processing and consent requirements

Output

MS25 Annex 1 (May 2026); country legal profiles for D5.2

Sources: [1]

How countries enable data linkage: examples

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Norway

A Cancer Registry regulation authorises inclusion and linkage of screening data. Identifiers for normal results may be kept without consent unless the person opts out; then the data are deleted within six months.

Ireland

A data protection impact assessment is needed for linkage within the HSE. Data-sharing agreements are used outside it.

Lithuania

Linkage with cause-of-death data is done on the protected platform of the National Data Agency.

Croatia

Linkage between screening and cancer registries is possible with ethics committee approval.

Slovenia

The law is unclear on cause-of-death data. An amendment has been proposed but not yet adopted.

Spain (Madrid)

Linkage with death records generally requires explicit consent unless another legal basis applies, with strict purpose and confidentiality conditions.

Source: MS25, Annex 1 [1] (respondents' descriptions of national legislation)

Country overview (1/2)

Country	Legislation beyond GDPR	Linkage: cancer registry	Linkage: cause of death	Opt-in consent required for
Austria	General	–	–	–
Belgium	Specific (1 region)	Permitted*	Restricted	–
Croatia	General	Permitted (ethics approval)	Restricted	**QA**
Cyprus	–	Restricted	–	–
Czechia	Specific	Permitted*	Permitted*	–
Denmark	General	–	–	–
Finland	General	Permitted*	–	–
France	General	Restricted	Permitted (SNDS)	–
Germany	General	–	Restricted	–
Greece	–	Restricted	Restricted	–
Hungary	General	Restricted	Restricted	**Registration, research**
Iceland	General	Permitted*	Permitted*	–
Ireland	Specific	Permitted*	Restricted	**Research**
Italy	–	–	Restricted	–

*Source: MS25 survey and Annex 1 [1]. – = not reported in MS25 (not the same as 'no'). * Annex 1 cites a national framework allowing individual linkage. 'General' = general health-data law, no screening-specific law.*

Country overview (2/2)

Country	Legislation beyond GDPR	Linkage: cancer registry	Linkage: cause of death	Opt-in consent required for
Latvia	General	Permitted (one direction)	Restricted	–
Lithuania	General	Permitted*	Permitted (secure platform)	–
Malta	General	–	–	–
Moldova	Specific	–	Restricted	**Registration, QA, research**
Netherlands	–	–	Permitted*	–
Norway	Specific	Permitted*	Permitted (some limits)	–
Poland	General	Restricted	Restricted	**QA, research**
Portugal	General	–	Restricted	–
Romania	General	Permitted*	Restricted	**Registration, QA, research**
Slovakia	General	–	–	–
Slovenia	Specific	Permitted*	Unclear (law change proposed)	–
Spain	7 regions general, 2 specific	Restricted in 2 regions	Restricted in 1 region	**Research (1 region)**
Sweden	General	–	–	**QA, research**
Ukraine	General	–	Permitted*	–

*Source: MS25 survey and Annex 1 [1]. – = not reported in MS25 (not the same as 'no'). * Annex 1 cites a national framework allowing individual linkage. 'General' = general health-data law, no screening-specific law.*

Tools 2–3: key messages from MS25

Convergence, with exceptions

Most countries process screening data under general health-data law. Only about one in five has screening-specific legislation.

Linkage is uneven

Two-thirds can link screening and cancer registries, but only half can link to cause-of-death registries.

Consent varies by purpose

Opt-in consent is rare for registration (7.7%) but more common for research (18%). Dynamic consent is not yet in use.

Genetic data are rare

84.6% of responses report no genetic data in screening, so rules on returning results are still to be built.

Substantial legal heterogeneity may impede cross-border data sharing.

Next: guide data collection for the third screening report on the ECIS platform, identify gaps and priority areas for monitoring, and deepen the analysis in D5.2 (M36).

Sources: [1]

Tool 4 · Independent legal review (S5.1)

4 *An external legal view on ELSI in cancer control and data sharing*

Subcontract

How it works

- Provider selected through an open call
- Subcontracting coordinated by DYPEDE
- Contributes to the ELSI assessment
- Prepares a dedicated stakeholder workshop

Across the three levels

Societal: national and EU legal frameworks

Institutional: obligations of programmes, registries and laboratories

Individual: rights of screening participants

Output

Legal input to D5.2 and the T5.1 workshop

Tool 5 · Stakeholder engagement

5 *What do the people who run, use and take part in screening think about sharing its data?*

Ongoing

How it works

- Workshop prepared with the legal partner
- Qualitative interviews and focus groups
- Short surveys where numbers are needed

Across the three levels

Individual: screening participants, patients and citizens

Institutional: programme coordinators, laboratories, professional bodies

Societal: policymakers and health authorities

Output

Stakeholder perspectives and recommendations for D5.2

Tool 6 · ELSI assessment framework

Privacy and confidentiality

Data anonymisation: effectiveness of anonymisation techniques

Access control: robustness against unauthorised disclosure

Consent management: clarity and completeness of consent forms

Equity and inclusion

Representation: diverse representation in datasets

Disparities: identify and address bias in collection and analysis

Benefit-sharing: equitable distribution of the benefits of sharing

Justice and fairness

Vulnerable populations: protect their rights and interests

Data ownership: clarify rights and responsibilities

Fair data use: guidelines for responsible use and dissemination

Trust and transparency

Openness: transparent data-sharing practices

Public engagement: public participation and input

Accountability: mechanisms for oversight

Sources: [5, 8, 11]

Tool 7 · Digital ELSI assessment tools

7 *Practical tools that let screening programmes check the ELSI of sharing their data*

Due: M36

How it works

- Built on the assessment framework (Tool 6)
- Populated with evidence from Tools 1–3
- Tested and refined with the legal review and stakeholders (Tools 4–5)
- Delivered in English

Proposed design, to be developed for D5.2.

Across the three levels

Individual: consent and return-of-results checks

Institutional: governance, linkage and data-protection checks

Societal: equity, trust and alignment with EU and national policy

Output

D5.2: Report of ELSI assessment, including the digital tools (M36)

Workplan and timeline

M6	M6–M24	M24–M30	M36	M36
Step 1	**Step 2**	**Step 3**	**Step 4**	**Step 5**
Protocol for measuring ELSI in cancer screening	Collection of information and legislation (MS25)	Data analysis	Report and white paper on ELSI in cancer screening (D5.2)	Systematic review or article (optional)

Where we are: MS25 submitted on 29 May 2026 (survey); its findings feed the analysis phase (M24–M30) and the D5.2 report and white paper at M36.

Sources: [1]

Take-home messages and next steps

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Sharing is valuable, but uneven

Pooled screening data improve evidence and programme quality, yet national rules on linkage and consent differ widely.

Consent and genetics need rules now

Dynamic consent is not yet in use and few programmes hold genetic data: rules must be ready before risk-based screening scales up.

AI and the EHDS raise the bar

The AI Act and the EHDS add new obligations. Programmes need practical checks, not only legal texts.

Towards D5.2 (M36)

Legal review, interviews and focus groups feed the ELSI framework and digital self-assessment tools.

How you can help

Take part in interviews and focus groups, name a contact person in your programme, and tell us about national legal changes (for example EHDS implementation) so that D5.2 reflects current law.

Sources: [1, 16, 17]

Partners and subcontracting

Task partners

Lead: DYPEDE (6th Health Region), Greece

Participants:

LU, ISPRO, PHC, NIPH (NO), CSF, AUSLRE, LSMUKK, IACS, ISS, IRFMN

MS25 contributors

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DYPEDE: A. Vantarakis (lead beneficiary)

CPO: C. Senore, V. Mitrugno, G. Ferrante, G. Casnati (survey lead)

CSF: A. Nevala, T. Sarkeala

Legal review subcontract (S5.1): see Tool 4

Questions for stakeholders



1. Which legal or ethical barriers most limit sharing of screening data in your country?
2. Which consent model suits re-use of screening data: specific, broad or dynamic?
3. Under what conditions should screening data be used to develop or test AI?
4. How should genomic or risk-based results be returned to participants?
5. What would most increase public trust in sharing screening data?

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Thank you

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References

[1] Bentzen HB, Ursin G, Vantarakis A, Senore C, Mitrugno V, Ferrante G, Casnati G, Nevala A, Sarkeala T. Collection of ELSI legislation from partners. EUCanScreen Milestone 25 (WP5, Task 5.1); 29 May 2026.

[2] National Human Genome Research Institute. 1990: ELSI founded. Online education kit. genome.gov/25520330.

[3] Zwart H, Nelis A. What is ELSA genomics? EMBO Rep. 2009;10(6):540–544.

[4] Stilgoe J, Owen R, Macnaghten P. Developing a framework for responsible innovation. Res Policy. 2013;42(9):1568–1580.

[5] Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 8th ed. New York: Oxford University Press; 2019.

[6] McLennan S, Fiske A, Celi LA, et al. An embedded ethics approach for AI development. Nat Mach Intell. 2020;2:488–490.

[7] Zack N. Ethics for Disaster. Lanham, MD: Rowman & Littlefield; 2009.

[8] Knoppers BM. Framework for responsible sharing of genomic and health-related data. HUGO J. 2014;8(1):3. doi:10.1186/s11568-014-0003-1.

[9] United Nations. Universal Declaration of Human Rights. Paris; 1948. Article 27.

[10] Kaye J, Whitley EA, Lund D, Morrison M, Teare H, Melham K. Dynamic consent: a patient interface for twenty-first century research networks. Eur J Hum Genet. 2015;23(2):141–146.

[11] Wilkinson MD, Dumontier M, Aalbersberg IJ, et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data. 2016;3:160018.

[12] Smit AK, Gokoolparsadh A, McWhirter R, et al. Ethical, legal, and social issues related to genetics and genomics in cancer: a scoping review and narrative synthesis. Genet Med. 2024;26(12):101270.

[13] Regulation (EU) 2016/679 (General Data Protection Regulation). OJ L 119, 4.5.2016.

[14] Regulation (EU) 2022/868 (Data Governance Act). OJ L 152, 3.6.2022.

[15] Council Recommendation of 9 December 2022 on strengthening prevention through early detection: a new EU approach on cancer screening (2022/C 473/01). OJ C 473, 13.12.2022.

[16] Regulation (EU) 2024/1689 (Artificial Intelligence Act). OJ L, 12.7.2024.

[17] Regulation (EU) 2025/327 (European Health Data Space). OJ L, 5.3.2025.

[18] Strech D, Sofaer N. How to write a systematic review of reasons. J Med Ethics. 2012;38(2):121–126.