

Bridge-Health Project Cyprus Meeting 21st September 2017

Privacy and Ethics Impact and Performance Assessment (PEIPA)

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BACKGROUND

- ▶ The BRIDGE-Health project aims to create European health information (EU-HI) and data generation networks to support evidence-based health policy and research for the EU and Member States
- ▶ **Among objectives:** To address ethical and legal issues associated with the collection and use of health data:
 - ▶ **Privacy and Ethics Impact and Performance Assessment (PEIPA)**, modified methodology of the Privacy Performance Assessment developed and implemented in the EUBIROD project ⁽¹⁻²⁾

⁽¹⁾ Di Iorio CT et All. Cross-border flow of health information: is 'privacy by design' enough? Privacy performance assessment in EUBIROD. Eur J Public Health. 2013;23(2):247-53.

⁽²⁾ Di Iorio CT et al. Privacy Impact Assessment Report: "Privacy Performance Assessment" of EUBIROD Registers, EUBIROD Consortium, March 2012 Update. Available at: http://www.eubirod.eu/documents/downloads/D5.2_final_update_2012.pdf

PEIPA Methodology

- ▶ The PEIPA methodology consists of the following steps:
 - ▶ Step 1: Identification and definition of key elements of ethics and privacy/data protection (Ethics and Privacy Factors)
 - ▶ Step 2: Adoption of a Targeted Tool (PEIPA questionnaire) and nomination of the Advisory Panel of Experts
 - ▶ Step 3: Analysis of ethics and privacy factors and variability of approaches at the European level
 - ▶ Step 4: Final Report

Step 1: Identification and Definition of Privacy and Ethics Factors

Step 1 involved:

- ▶ Description and analysis of EUBIROD, ECHO, and EUROHOPE data sources and data flows
- ▶ Review of privacy and ethics literature to identify privacy and ethical principles/norms involved in data processing operations occurring within registers/databases/health information systems involved
- ▶ Ethics and Privacy Framework:
 - ▶ EUBIROD Privacy Impact Assessment Report
 - ▶ OECD Health Information Infrastructure Report
 - ▶ OECD, Health Data Governance Report
 - ▶ Recommendation of the OECD Council on Health Data Governance
 - ▶ Regulation (EU) 2016/679, General Data Protection Regulation
- ▶ Privacy and Ethics Factor Identification

Step 1: Identification and Definition of Privacy and Ethics Factors (2)

▶ **Privacy/data protection and ethics factors:**

- ▶ *Responsibility for Personal Data*
- ▶ *Collection and Use of Personal Data*
- ▶ *Consent,*
- ▶ *Data Sharing,*
- ▶ *Data Linkage*
- ▶ *Access and Accuracy of Personal Data*
- ▶ *Safeguarding Personal Data*
- ▶ *Anonymisation Process*
- ▶ *Openness, Transparency and Public Engagement*
- ▶ *Transparent Project Approval Processes*
- ▶ *Beneficence/Non Maleficence in Health Research Project Approval Processes*

Step 2: PEIPA Questionnaire

- ▶ **Scope:**

- ▶ To acquire detailed information on how data is processed by involved participants: EUBIROD, ECHO and EUROHOPE consortia.

- ▶ **Aims:**

- ▶ To determine the level of privacy protection and ethical principle compliance of registries/databases involved in the above consortia
- ▶ To evaluate how heterogeneous is the implementation of privacy-ethical principles/requirements among participating centres
- ▶ To identify key areas of concern in the implementation of privacy-ethical principles/requirements across participating centres
- ▶ To determine an optimal level of privacy and ethics (best practices) to be used as benchmarks for privacy/data protection and ethics clearance

Step 2: PEIPA Questionnaire (2)

The questionnaire is a core element of the PEIPA providing input for the privacy and ethics analysis

- ▶ Addressed to data controllers and/or data protection officers and/or chief executive officers responsible for data processing occurring in the registries/databases/information systems of the BRIDGE-Health consortia: ECHO, EUROHOPE and EUBIROD
- ▶ Administered by Serectrix snc on behalf of the University of Tor Vergata (Italy), in collaboration with Consortia Coordinators, who facilitated submission and collection of the questionnaires to and from participating centres.
- ▶ Composed of 11 sections (factors), each containing a specific number of questions (sub-factors).

Step 2: Advisory Panel of Experts

▶ Ad hoc Advisory Panel of Experts nominated:

- ▶ For the revision of the Privacy and Ethics Impact and Performance Assessment (PEIPA) process
- ▶ To ensure that resulting benchmarks for privacy/data protection and ethics clearance are widely agreed upon and are based on objective measurements

▶ Composition:



Surname	Name	Institution	Country
Smith	David	Former Deputy UK Information Commissioner	UK
Hamalainen	Paivi	National Institute of Health and Welfare (THL)	Finland
Siano	Manuela	Data Protection Authority	Italy
De Marco	Dorotea	Data Protection Authority	Italy
Oderkirk	Jillian	OECD Health Division	France
de Lusignan	Simon	University of Surrey	UK

Step 3: Analysis of Ethics and Privacy Factors

- ▶ **Questionnaires' responses** analysed through a qualitative-quantitative methodology developed in the EUBIROD project and further tailored for the BRIDGE-Health Privacy and Ethics Impact and Performance Assessment (PEIPA)
- ▶ **Standardized coding** has been applied to deliver a qualitative-quantitative analysis for all questions and factors included in the questionnaire

Step 2: Scoring System

- ▶ Revised and agreed with the Advisory Panel of Experts
- ▶ **Scope:**
 - ▶ To ascertain the adherence to privacy and ethics principles or norms of selected processing operation undertaken by members of ECHO, EUROHOPE and EUBIROD consortia.
- ▶ **Methodology:**
 - ▶ original responses (YES-NO-N/A) coded by assigning a mark of 1 to any privacy protective conduct regardless of a YES-NO-N/A response
 - ▶ weighed marks have been also assigned whether necessary, as specified in the scoring tables
 - ▶ a mark of zero to any non-privacy protective practice
 - ▶ missing and N/A responses have been excluded by the calculation of mean, median and total scores of the sample, unless the scoring tables have assigned to N/A a different value (see appendix 2)
 - ▶ Factors scores are computed as the linear sum of recoded values (of the original responses).
 - ▶ Scaled factors are computed as a percentage of each factor score on the total attainable score
 - ▶ The overall level of privacy and ethics protection has been computed as the average of all scaled factors for each participating centre

Scoring Table: Example

- ▶ **Table 5: Data Linkage**
- ▶ **(Max Score = 10)**

Questions For Analysis	Yes	No	N/A
5.1	1	1	
5.2	0	1	
5.3	0	1	
5.4	0	1	
5.5	1	0	
5.6	1	0	
5.7	1	0	
5.8	1	0	
5.9	1	0	
5.10	1	0	

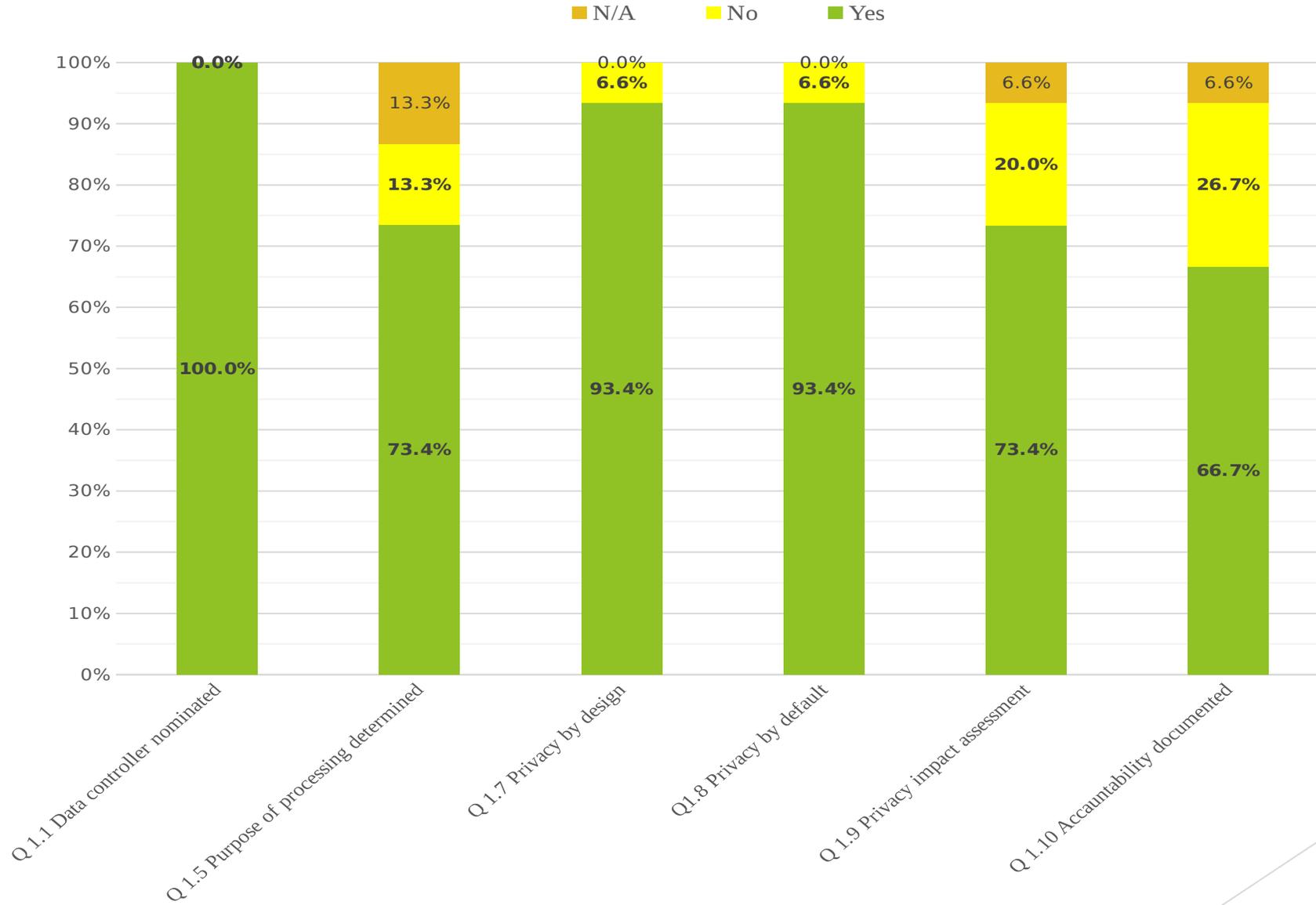
PEIPA Results

- ▶ Results are relative to the N=15 respondents to the PEIPA questionnaire
- ▶ Results are presented into 4 sub-sections:
 - 1. Main findings from single questions:**
 - overall percentage of YES-NO-N/A responses registered by the whole sample for each of the selected questions
 - 2. Factors:**
 - scaled scores achieved by the whole sample in each privacy and ethics factor. This sub-section provides an evaluation of the adherence to privacy/data protection and ethics principles of responding centres in any factor identified
 - 3. Overall privacy performance evaluation:**
 - overall level of privacy/data protection and ethics achieved by the whole sample
 - Privacy/Data protection and Ethics Performance by Consortia
 - 4. Privacy/Data protection and Ethics Profile of Participating Centres**

Results: Main Findings from single questions

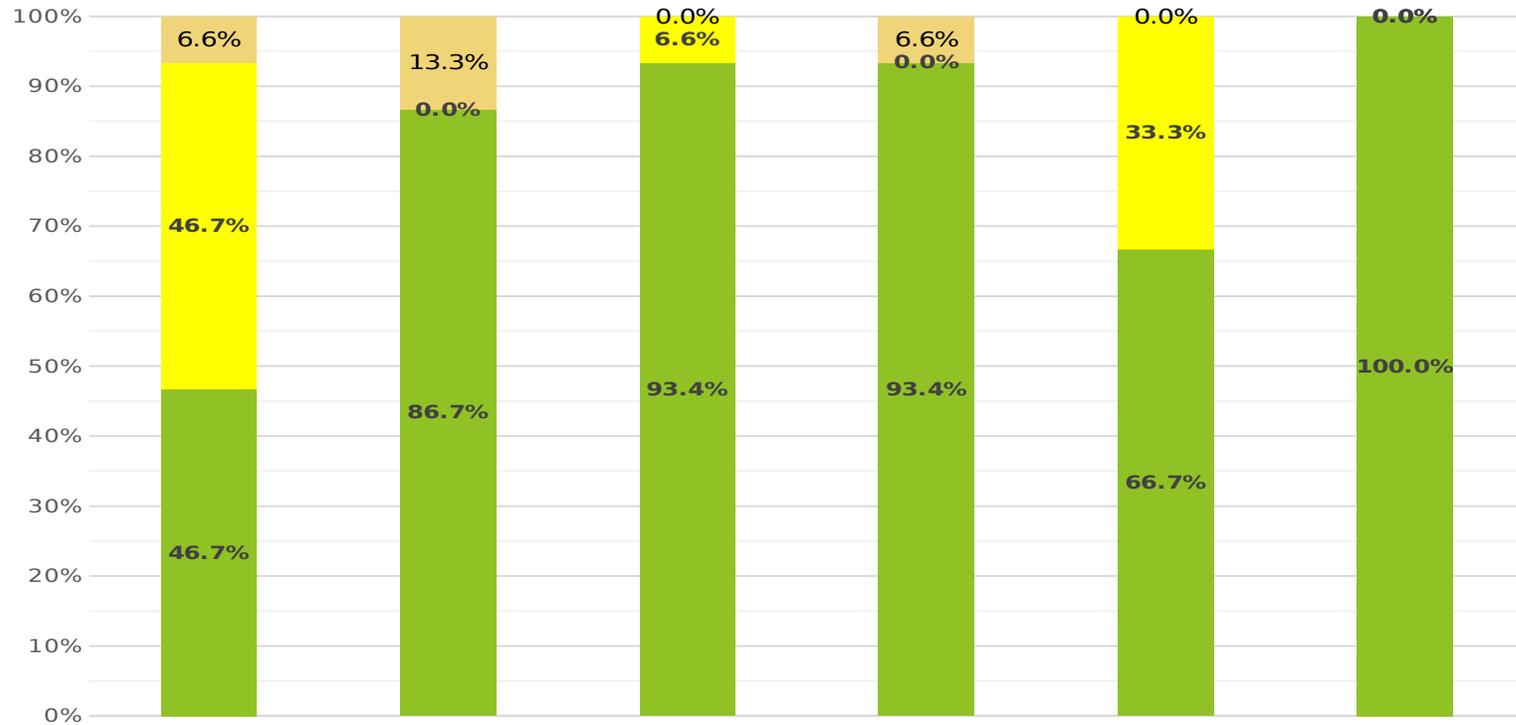
- ▶ The following factors are presented in details:
 - ▶ Responsibility for Personal data
 - ▶ Collection and Use of Personal Data
 - ▶ Consent
 - ▶ Data Sharing
 - ▶ Data Linkage
 - ▶ Safeguarding Personal Data
 - ▶ Anonymisation Process

Responsibility for Personal Data



Collection and Use of Personal Data

N/A No Yes



Q 2.2 Collection with consent

Q 2.3 All PD collected necessary

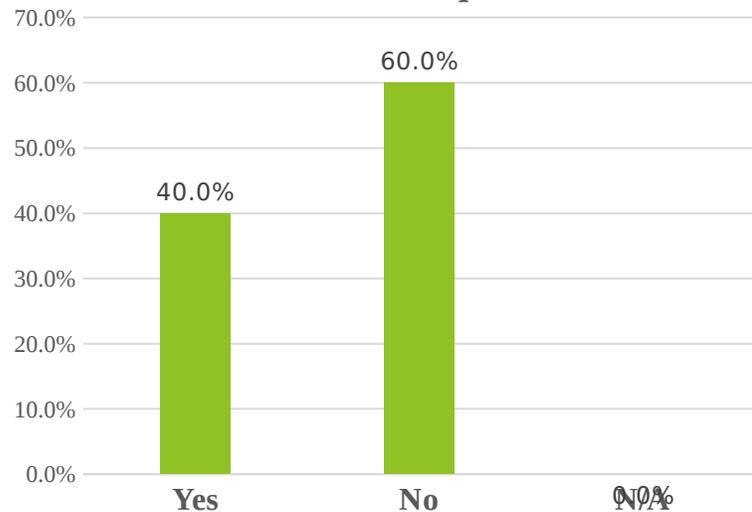
Q 2.4 Use for secondary purposes allowed for approved research

Q 2.5 Secondary purposes compatible with original purposes

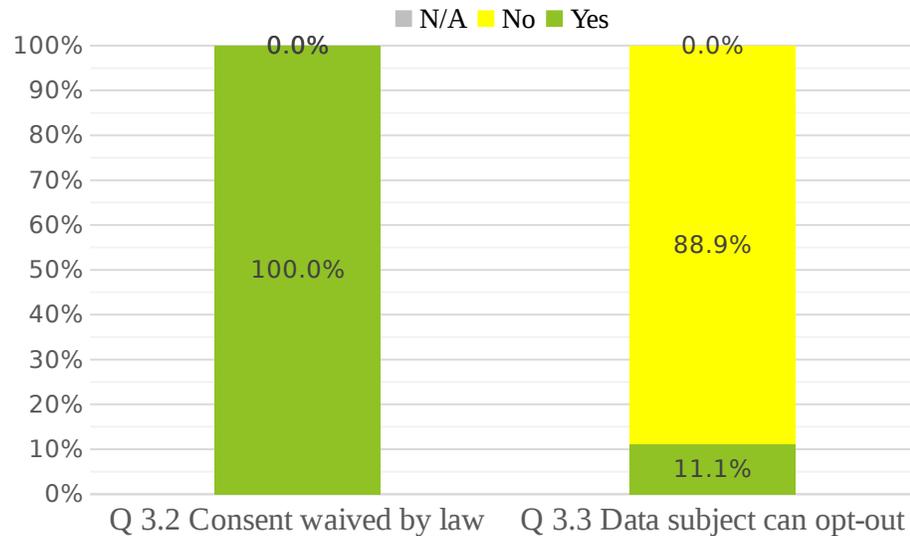
Q 2.6 Data used to report on healthcare quality

Q 2.9 Data de-identified before used for secondary purposes

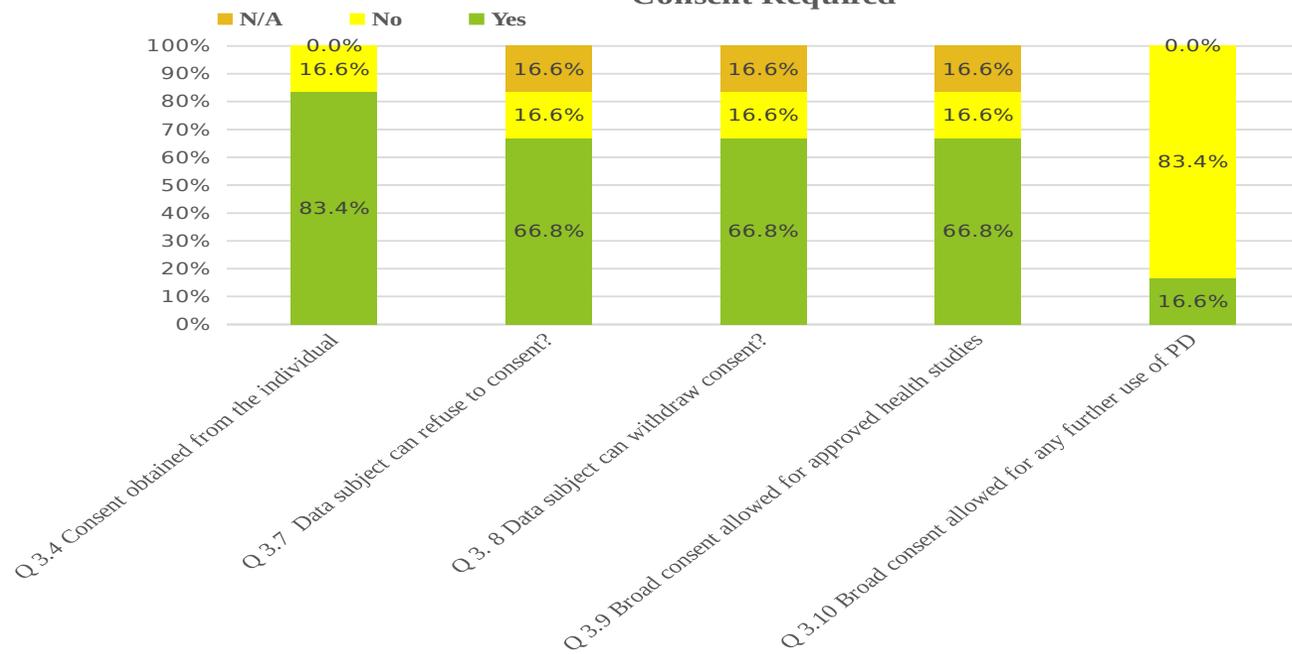
Is Consent Required?



Consent Not Required

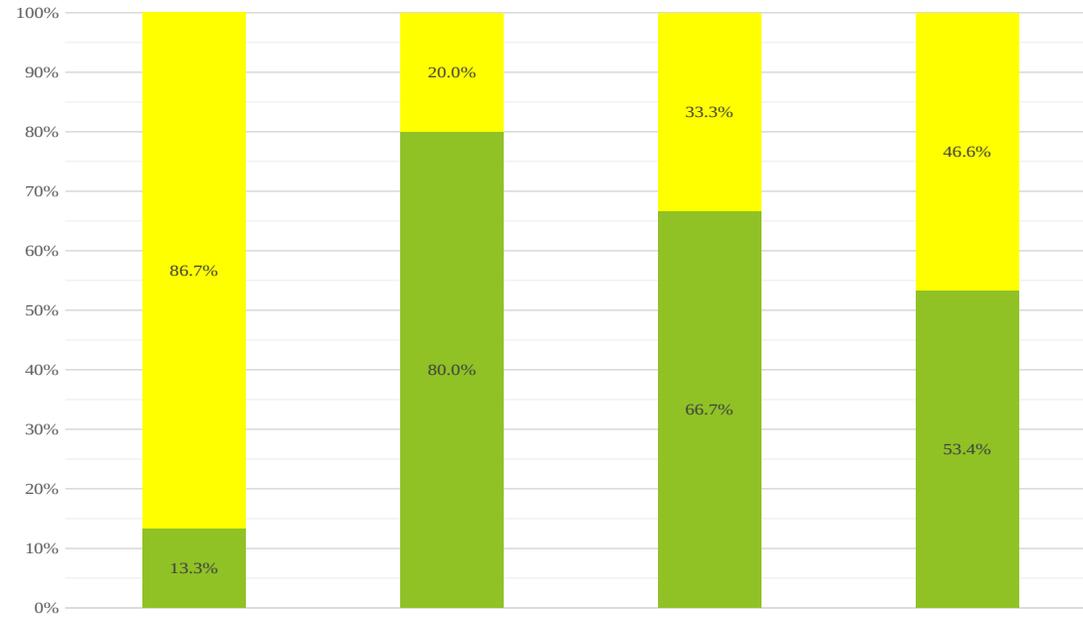


Consent Required



Data Sharing

■ No ■ Yes



Q 4.1 Data controllers allowed to share identifiable PD for research with public authorities/academy

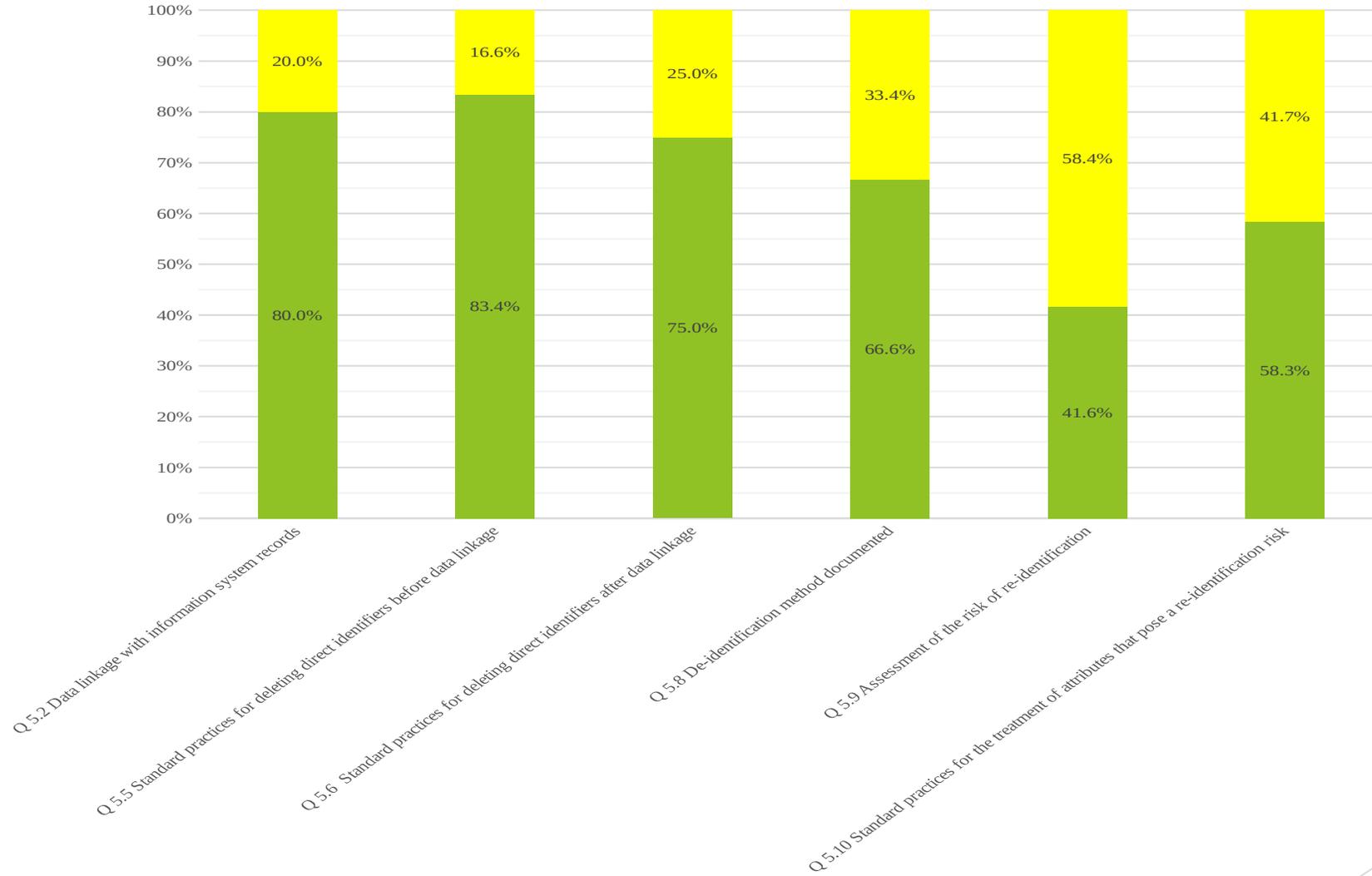
Q 4.2 Data controllers allowed to share de-identified data with public authorities/academy

Q 4.4 Cross-border data flow of identifiable data with public authorities/academy

Q 4.5 Standard data sharing agreement

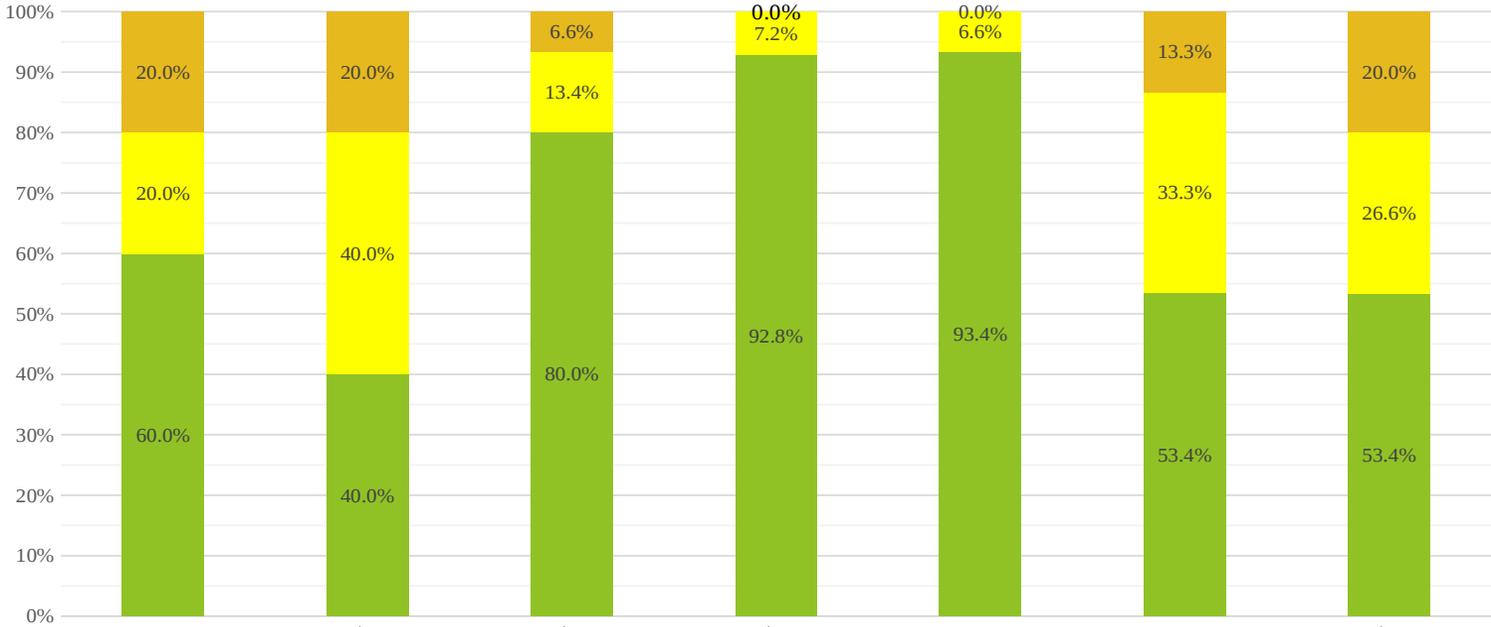
Data Linkage

■ No ■ Yes



Safeguarding Personal Data

■ N/A ■ No ■ Yes



Q 7.1 Security measures compliant with international standards

Q 7.2 Compliance certified

Q 7.3 Security procedures documented

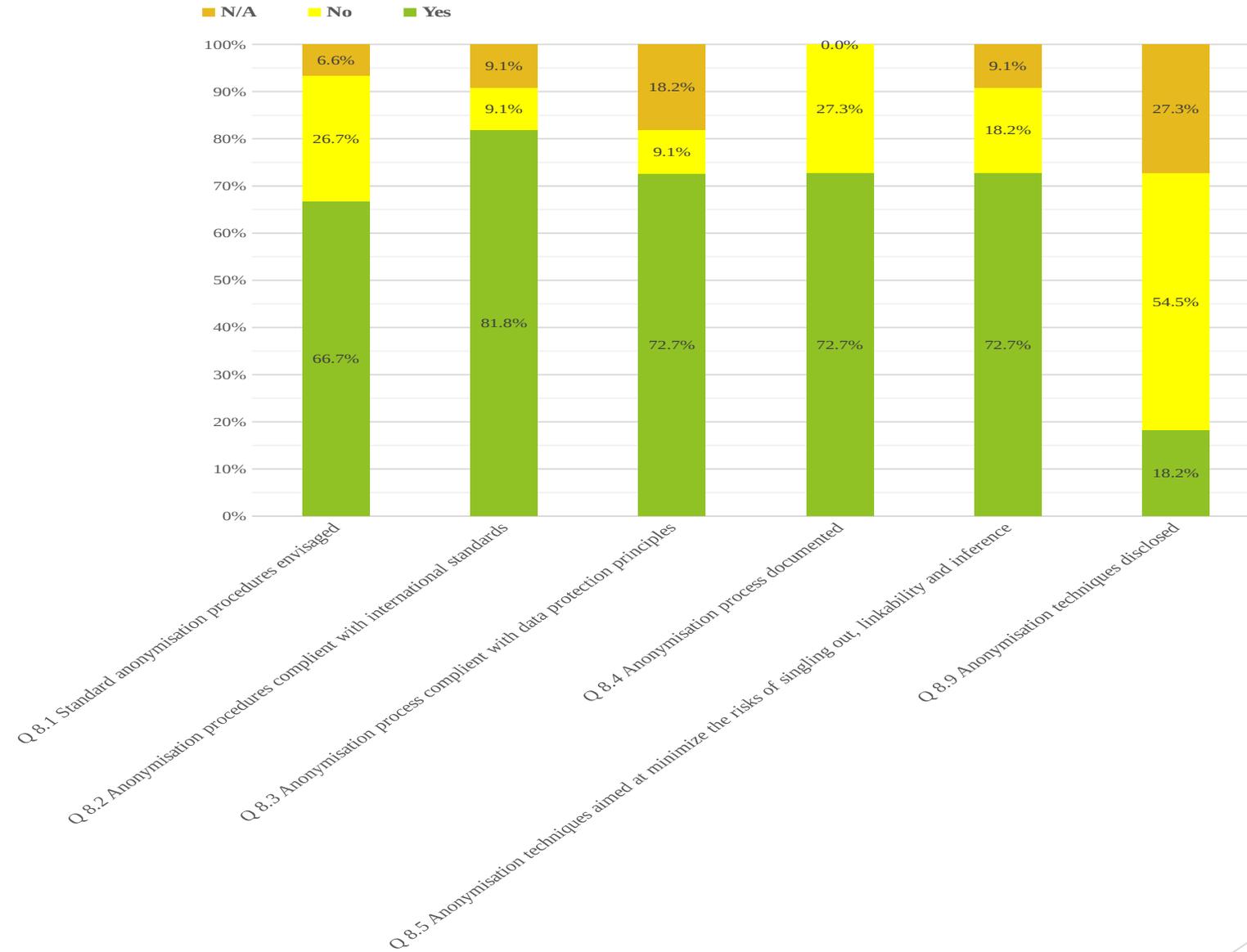
Q 7.5 System or record management process implemented

Q 7.8 Contingency plan for security breaches

Q 7.9 Plan for the notification of security violations

Q 7.10 Quality assurance and audit programs envisaged

Anonymisation Process

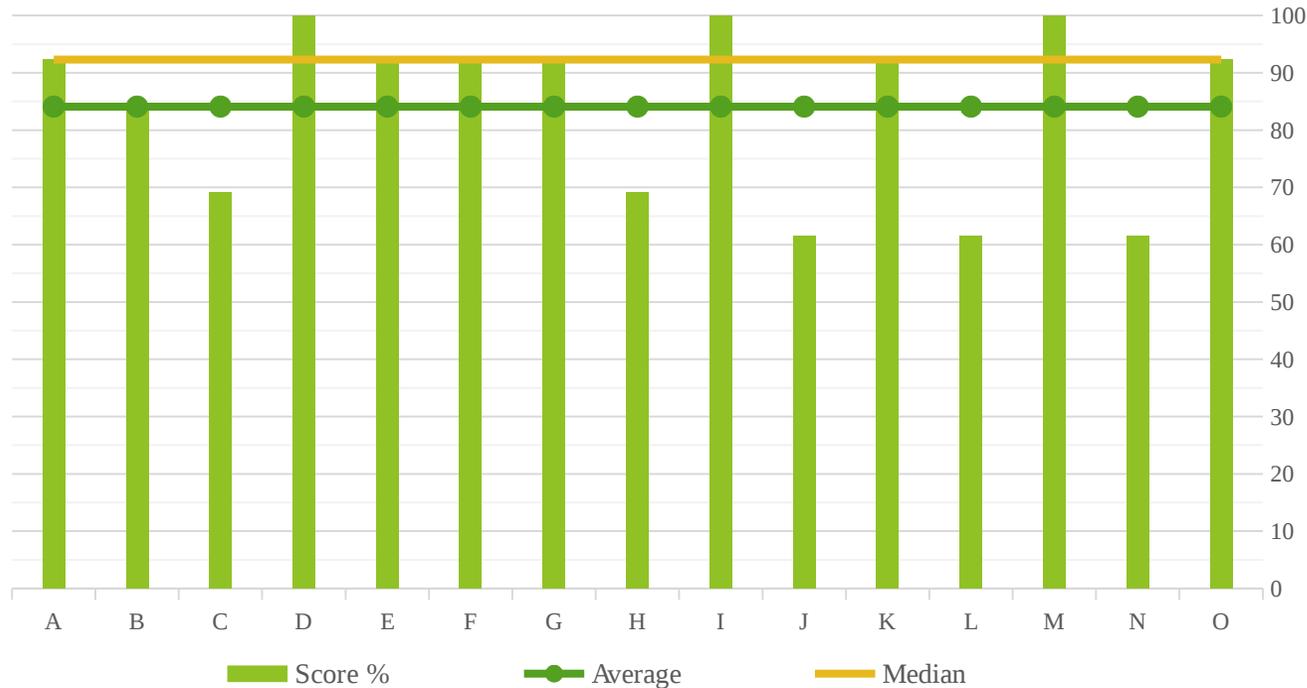


Results by Factor

- ▶ Each factor (e.g. data linkage) is composed of several questions (sub-factors; e.g. is record linkage performed using the registry/information system records?) to which scores have been assigned according to the agreed scoring system
- ▶ The sum of scores obtained in all sub-factors for a given factor provides an assessment of the privacy/data protection and ethics compliance with EU legislation and relevant principles and guidelines by factor
- ▶ The absolute values obtained as a sum of the individual components (questions, or sub-factors) are presented as standardized values, expressed as a percentage of the maximum score achievable for each factor
- ▶ A graphical display of standardized values is provided for each factor
- ▶ Overall results for each factor are evaluated according to the following range of scores:

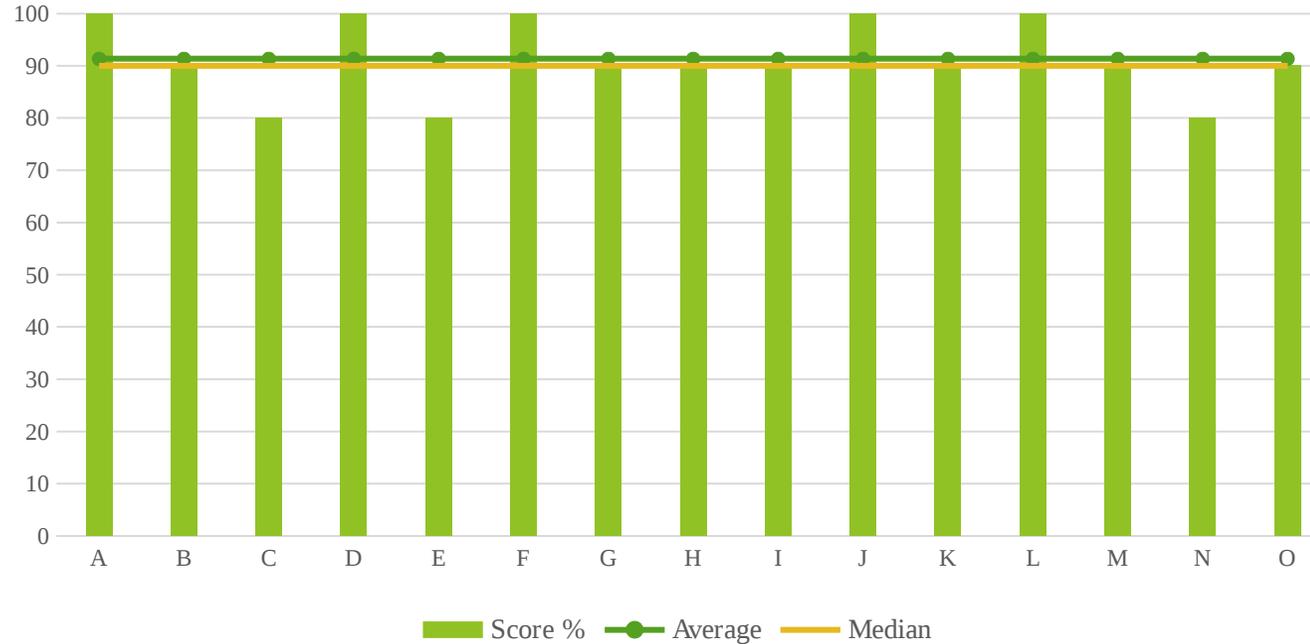
Score	Range
Excellent	Median value ranges from 90% to 100%
Very good	Median value ranges from 80% to 89%
Good	Good: the median value ranges from 70% to 79%
Fair	Median value ranges from 50% to 69%
Poor	Median value ranges from 40% to 49%
Very poor	Median value is equal or below the 39%

Responsibility for Personal Data

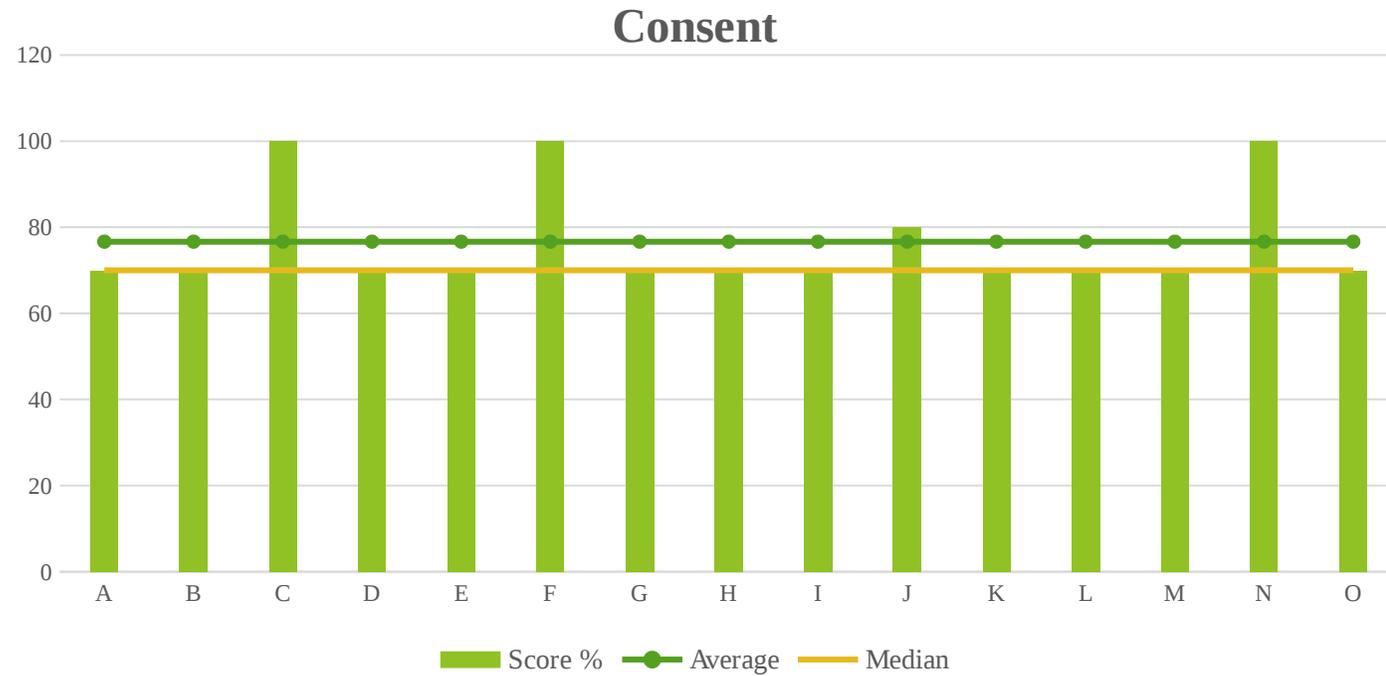


- ▶ Results: fairly homogeneous
- ▶ Max Score (N=13): reached by 20 % of sample
- ▶ The 66.6% of centres scored above the mean value of the sample (84%)
- ▶ Median value = 92%: **Excellent compliance** with privacy/data protection principles
- ▶ Range: 62% - 100%

Collection & Use of Personal Data

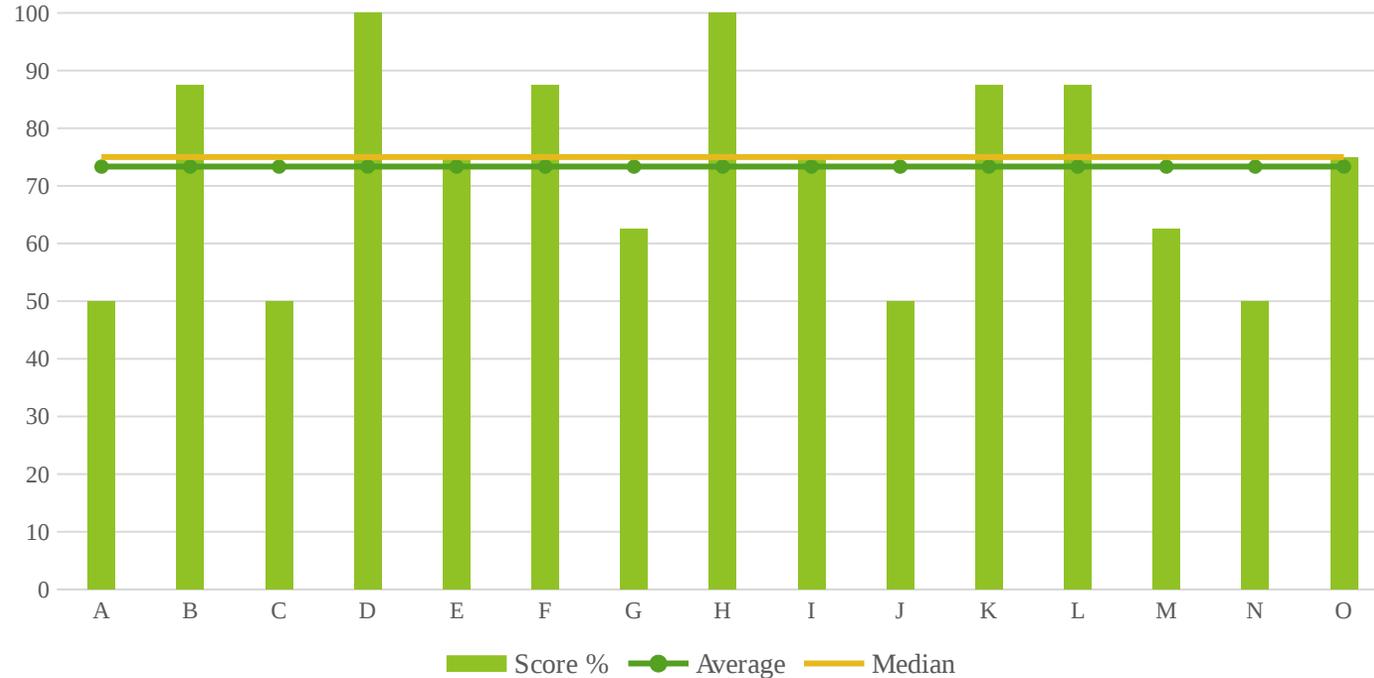


- ▶ Results: homogenous
- ▶ Max score: reached by the 33.3% of the sample
- ▶ The 33.3% of the sample scored above the average value (91%)
- ▶ Median value = 90%: **Excellent compliance** with privacy/data protection principles
- ▶ Range of scores: 80% - 100%



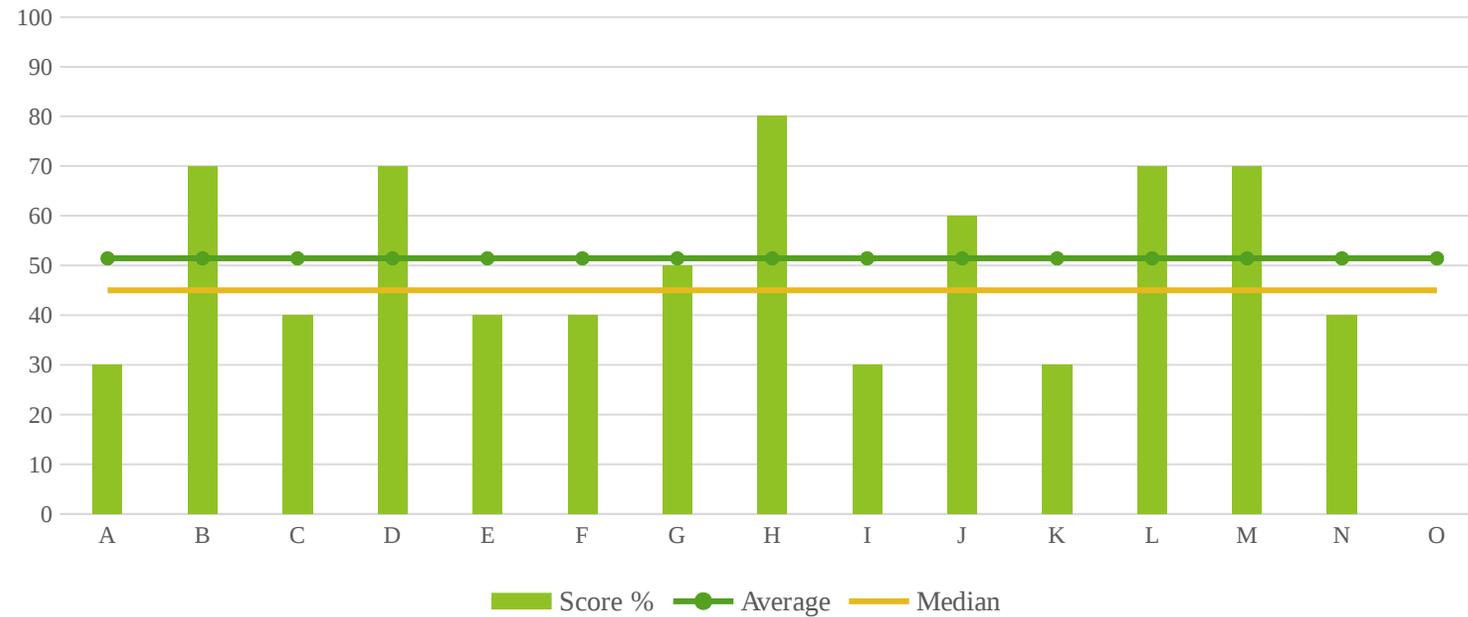
- ▶ Results: homogenous
- ▶ Max score: obtained by the 21.4% of the sample
- ▶ The 28.6% of the sample scored above the average value (77%)
- ▶ Median value = 70%: **Good compliance** with privacy/data protection principles
- ▶ Range of scores: 70% - 100%

Data Sharing



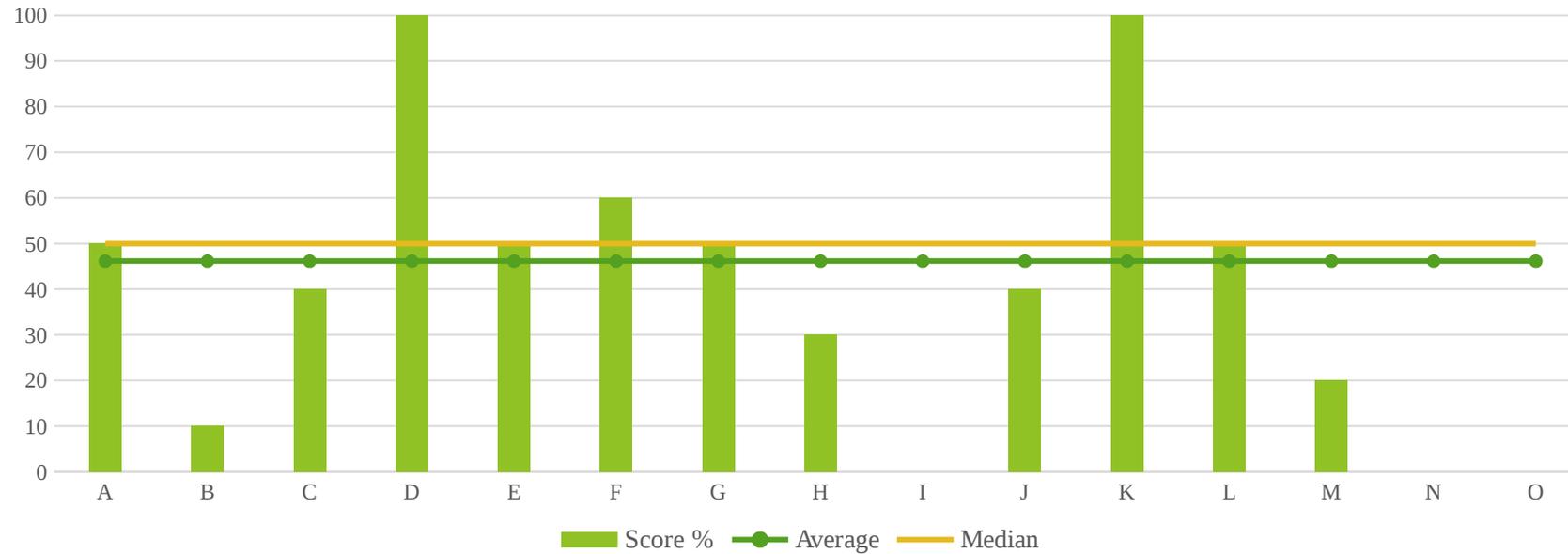
- ▶ Results: fairly homogeneous
- ▶ Max score: by 13.3% of the sample
- ▶ The 60% of the sample scored above the average value (73%)
- ▶ Median value = 75%: **Good compliance** with privacy/data protection principles
- ▶ Range of scores: 50% - 100% (more scattered distribution of scores/values)

Data Linkage



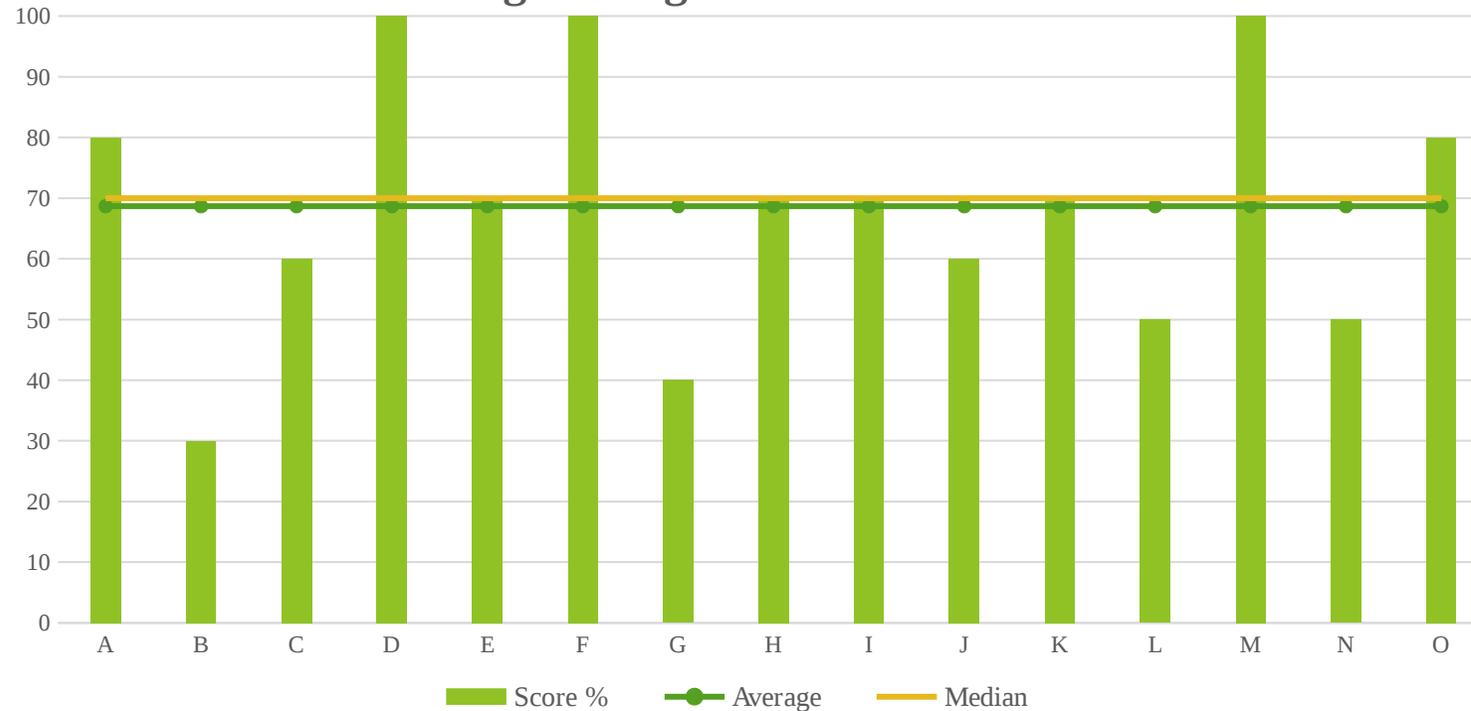
- ▶ Results: heterogeneous
- ▶ None of the centres obtained the maximum score for this factor
- ▶ The 40% of the sample scored above the average value (51%)
- ▶ Median value = 45%: **Poor compliance** of the sample with privacy/data protection principles
- ▶ Range of scores: 30% - 80%.

Access and Accuracy of Personal Data



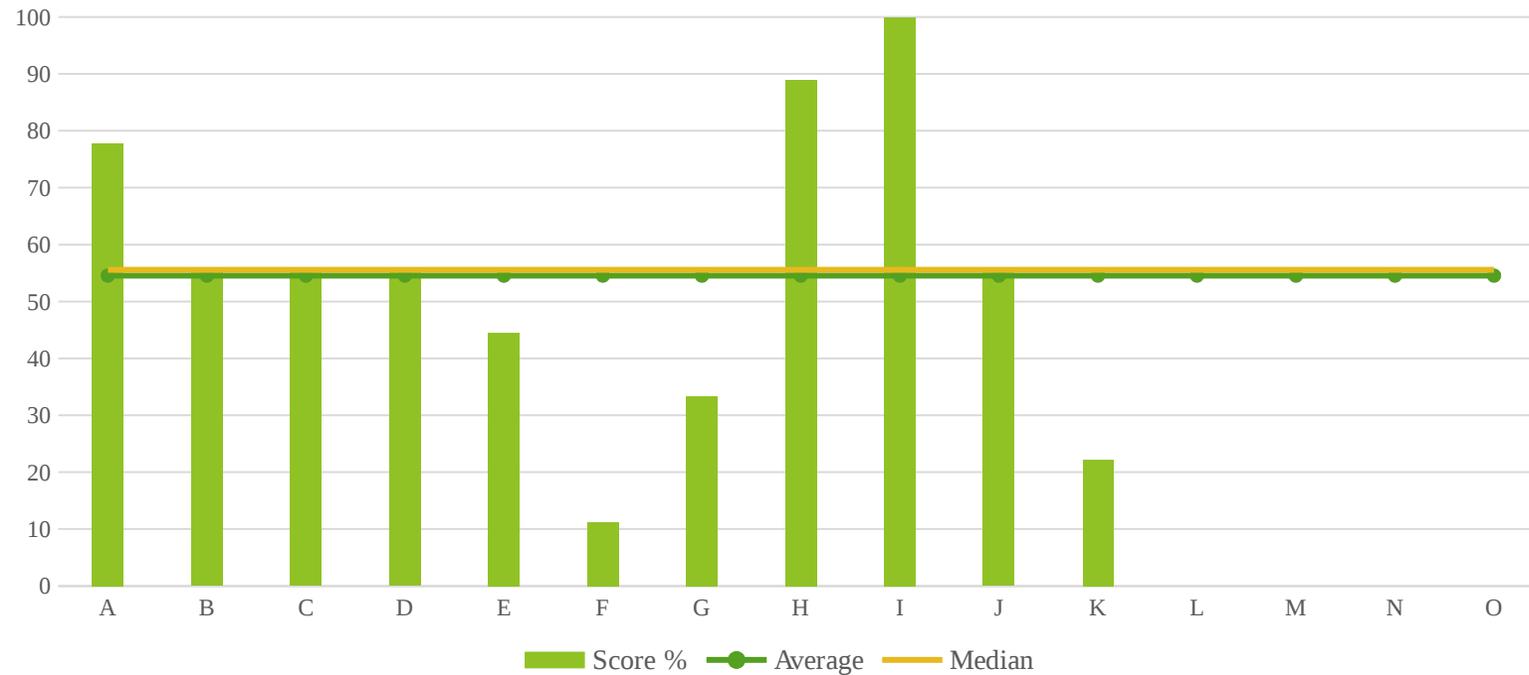
- ▶ Results: high degree of heterogeneity
- ▶ Only the 13.3% of centres obtained the maximum score
- ▶ The 46.6% of the sample scored above the average value (46%)
- ▶ Median value = 50%: **Fair compliance** of the sample with privacy/data protection principles
- ▶ Mean and median values are calculated on a sample of 13 out of 15 centres
- ▶ Range of scores: 0% - 100%

Safeguarding Personal Data



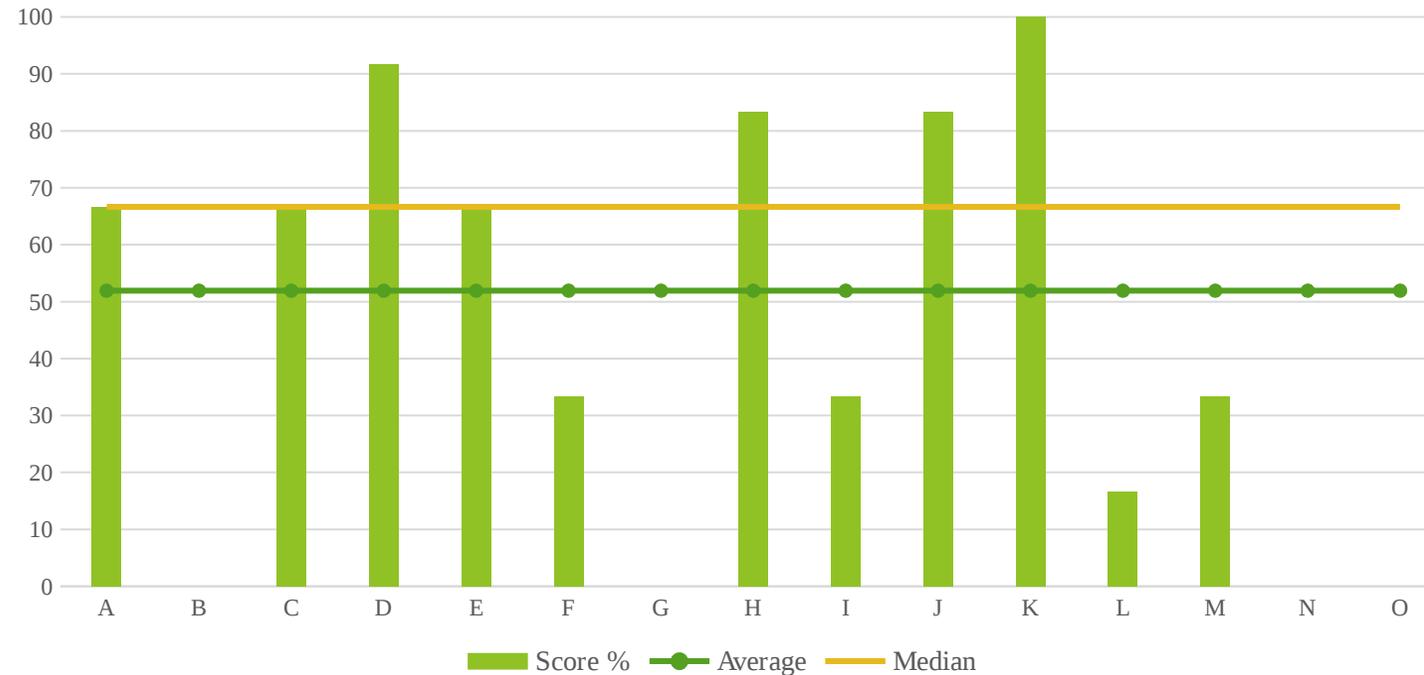
- ▶ Results: fairly heterogeneous
- ▶ Only the 20% of centres obtained the maximum score
- ▶ The 60% of the sample scored above the average value (69%)
- ▶ Median value = 70%: **Good compliance** of the sample with privacy/data protection principles
- ▶ Range of scores: 30% - 100%

Anonymisation Process



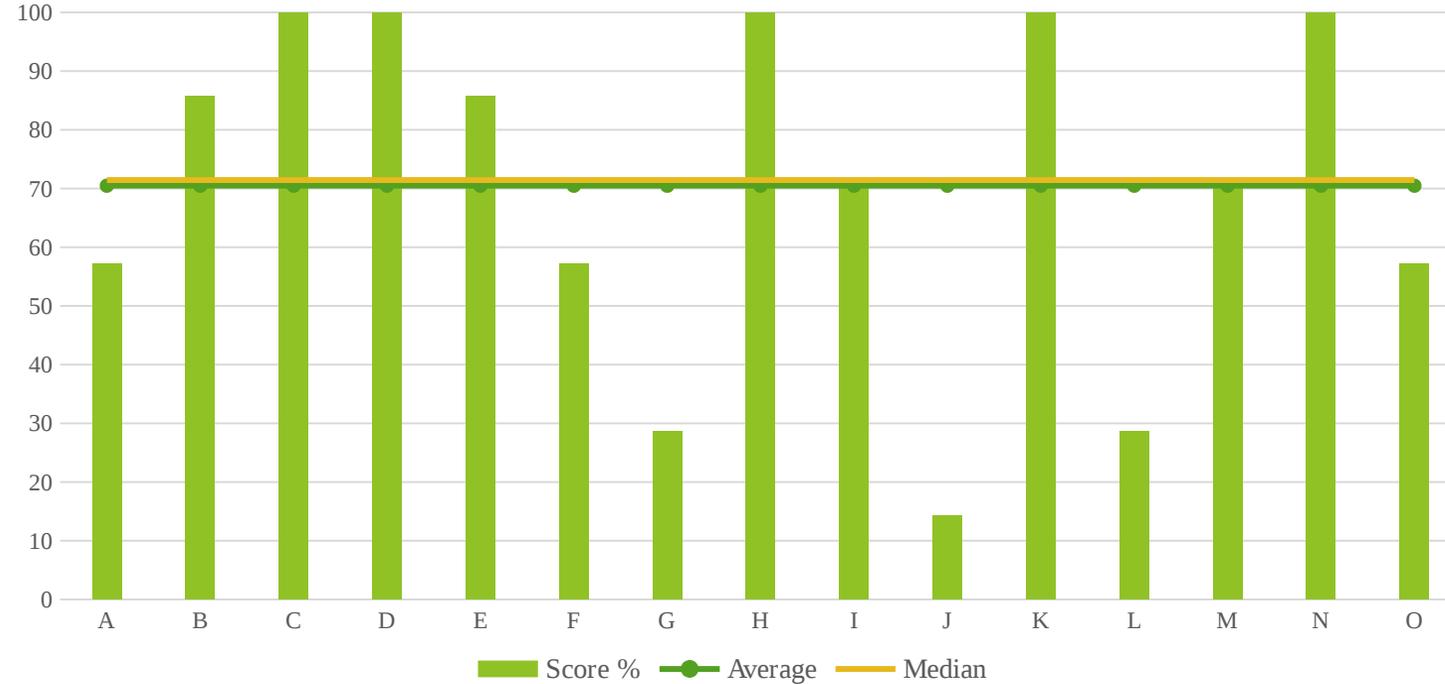
- ▶ Results: highly heterogeneous
- ▶ Only the 9.1% of centres obtained the maximum score
- ▶ The 63.6% of the sample scored above the average value (55%)
- ▶ Median value = 56%: **Fair compliance** of the sample with privacy/data protection principles
- ▶ Mean and median values are calculated on a sample of 11 out of the 15 centres
- ▶ Range of scores: 11% - 100%

Openness, Transparency and Public Engagement



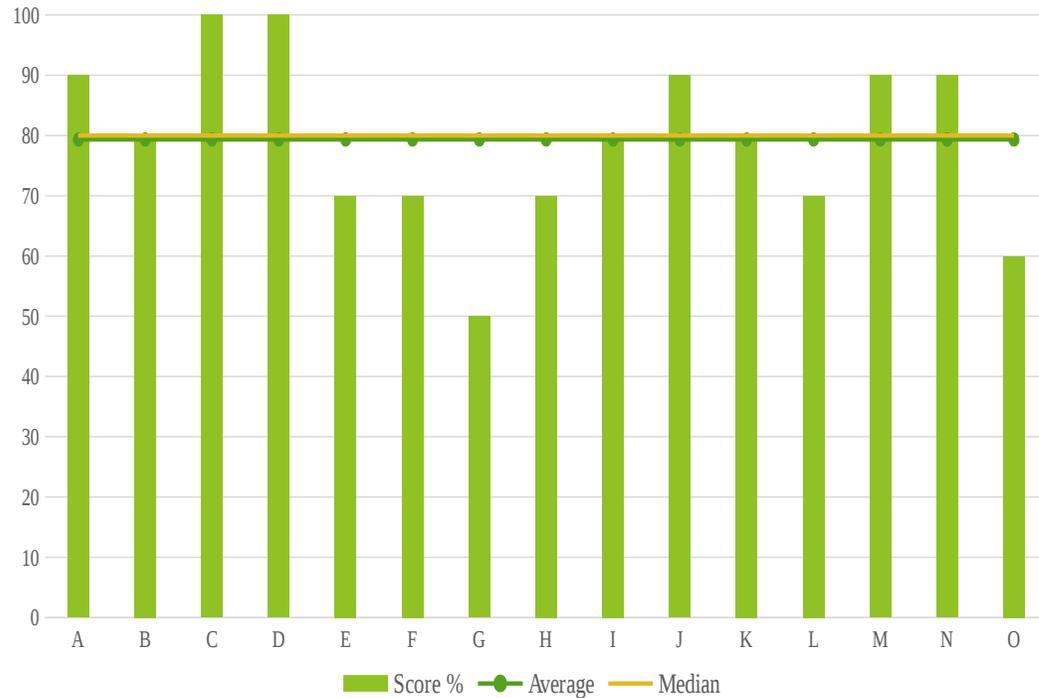
- ▶ Results: highly heterogeneous
- ▶ Only the 7.7% of centres obtained the maximum score
- ▶ The 53.8% of the sample scored above the average value (52%)
- ▶ Median value = 67%: **Fair compliance** of the sample with privacy/data protection principles
- ▶ The mean and median values are calculated on a sample of 13 out of the 15 centres
- ▶ Range of scores: 0% - 100%

Transparent Health Research Projects Approval Process



- ▶ Results: fairly heterogeneous
- ▶ The 33.3% of centres obtained the maximum score
- ▶ The 60% of the sample scored above the average value (70%)
- ▶ Median value = 71%: **Good compliance** of the sample with relevant principles
- ▶ Range of scores: 14% - 100%

Beneficence/Non-maleficence Principles in Health Research Project Approval Processes



- ▶ Results: fairly homogeneous
- ▶ The 13.3% of centres obtained the maximum score
- ▶ The 60% of the sample scored above the average value (79%)
- ▶ Median values = 80%: **Very good compliance** of the sample with relevant ethics principles
- ▶ Range of scores: 50% - 100%. Results highlights an overall in this factor

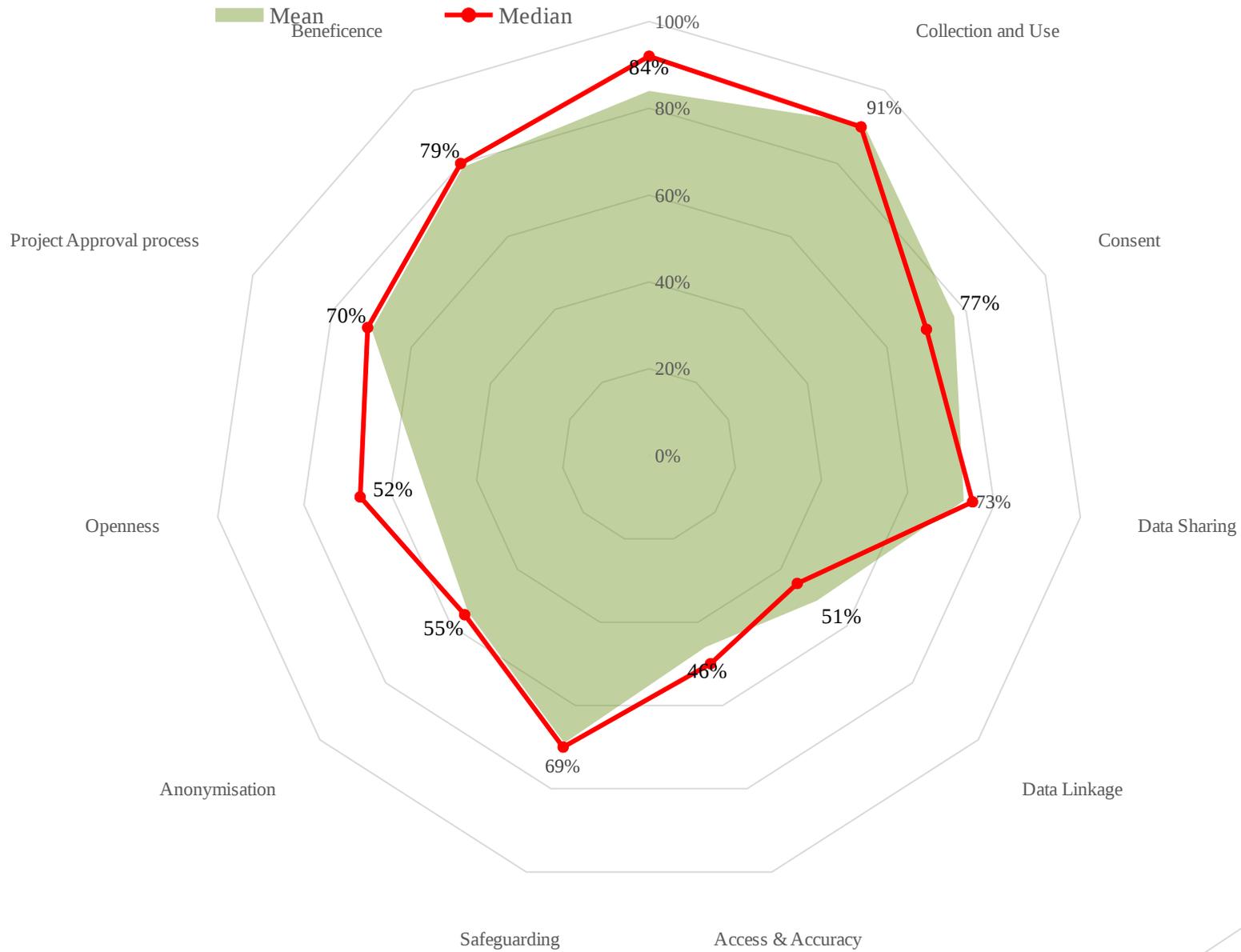
Standardized Comparison of Factor Results

- ▶ Median values show that the following areas should be regarded as the most problematic:
 - ▶ Data Linkage (45%)
 - ▶ Access and Accuracy (50%)
 - ▶ Openness, Transparency and Public Engagement (50%)
- ▶ The following factor, presenting a median equal to 56%, is also of concern:
 - ▶ Anonymisation
- ▶ The following factors showed a high variability of scores (range):
 - ▶ Data linkage (30%-80%)
 - ▶ Access and accuracy of personal data (0%-100%)
 - ▶ Safeguarding personal data (30%-100%)
 - ▶ Anonymisation process (11%-100%)
 - ▶ Openness, transparency and public engagement (0%-100%)
 - ▶ Transparent health research projects approval process (14%-100%)
 - ▶ Data sharing (50%-100%)
 - ▶ Beneficence/Non-maleficence Principles in Health Research Project Approval Processes (50%-100%)

Overall Privacy and Ethics Performance

- ▶ The average and median of scores obtained by the whole sample of BRIDGE-Health participating centres allows evaluating the overall level of privacy/data protection and ethics performance of the sample, observed against the highest attainable level of privacy protection and adherence to relevant ethical principles.
- ▶ The highest **average** score (91%) was reached by the sample with regard to the factor “collection and use of personal data”, followed by “responsibility for personal data” (84%), “beneficence” (79%), “consent” (77%) and “data sharing” (73%)
- ▶ The sample scored just above the 50% of the maximum score (mean values) in the following factors:
 - ▶ Anonymisation
 - ▶ Openness
 - ▶ Data linkage
- ▶ The sample scored below the 50% (mean values) in the following factors:
 - ▶ Access and accuracy of personal data

Overall Privacy and Ethics Performance

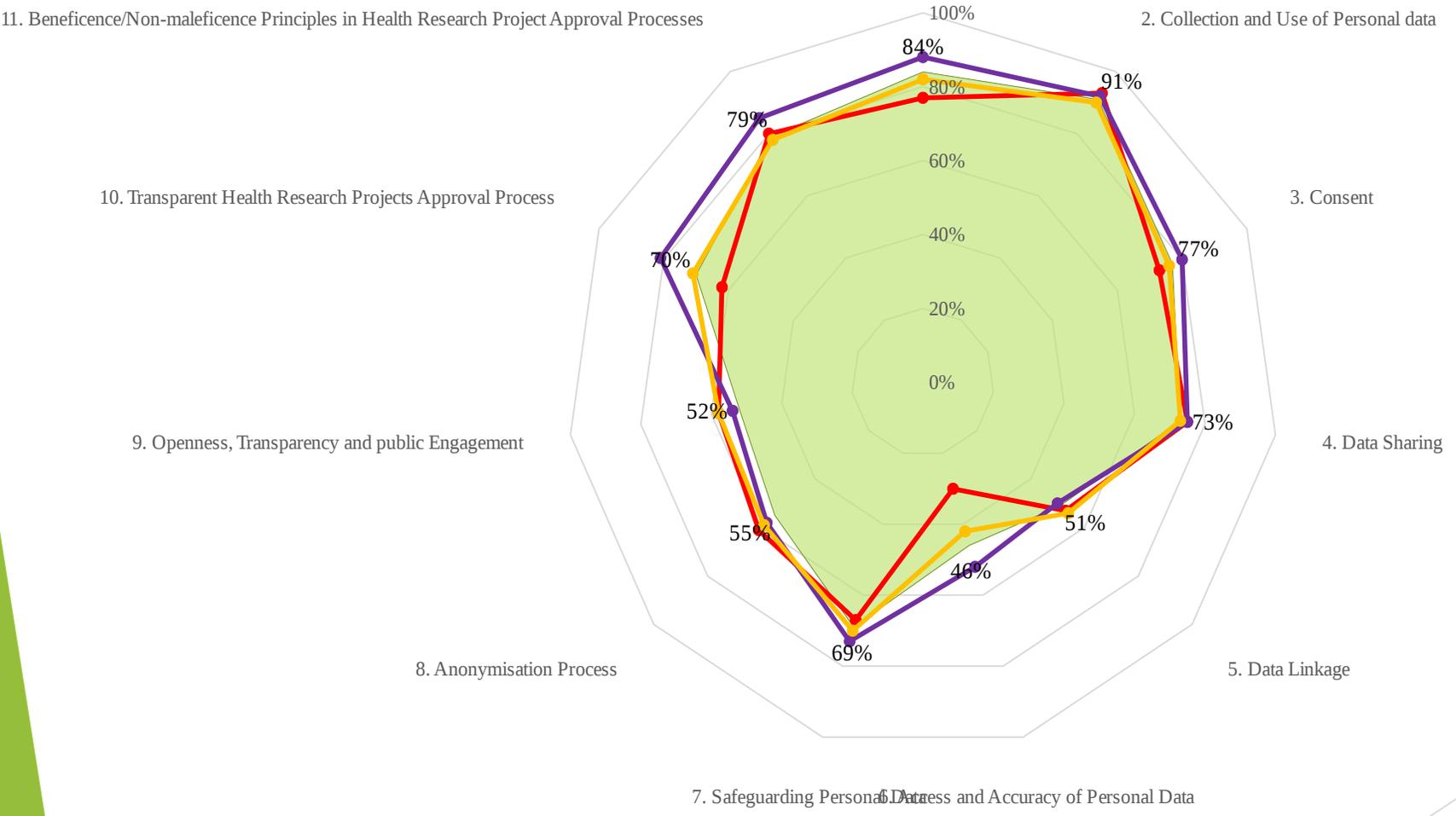


Privacy and Ethics Performance by Consortia

- ▶ The same graphical representation can be provided for each of the three consortia involved in the study
- ▶ The mean values reported by the ECHO, EUBIROD and EUROHOPE consortia are hereafter presented for each factor analysed

ECHO, EUBIROD and EUROHOPE Performance by Factor

■ Mean OVERALL
 ● Mean (ECHO)
 ● Mean (EUBIROD)
 ● Mean (EUROHOPE)



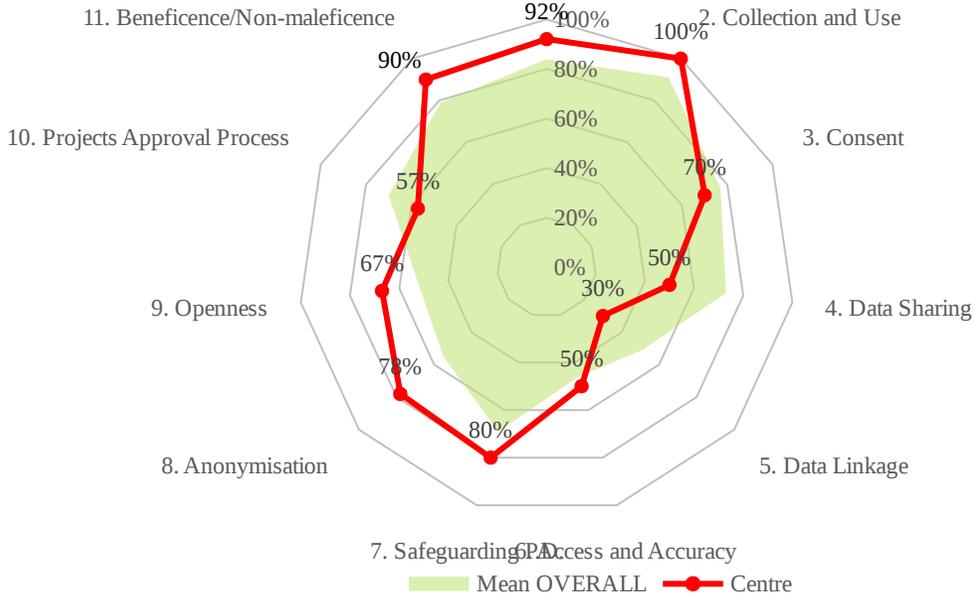
- The light green area highlights the mean results of the whole sample
- The red, violet and orange lines describe the results, by factor, of each consortia: ECHO, EUBIROD and EUROHOPE

Privacy and Ethics Profile of participating Centres



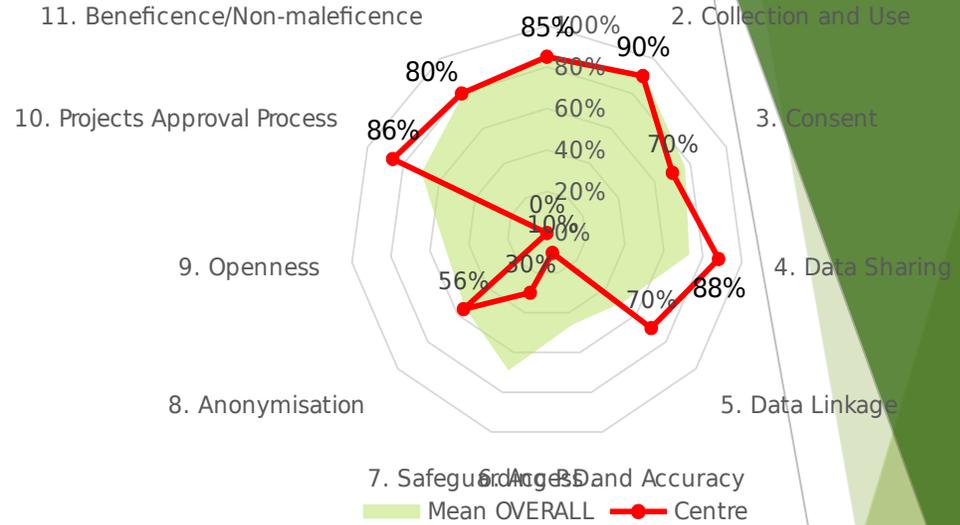
CENTRE "A"

1. Responsibility for P.D.



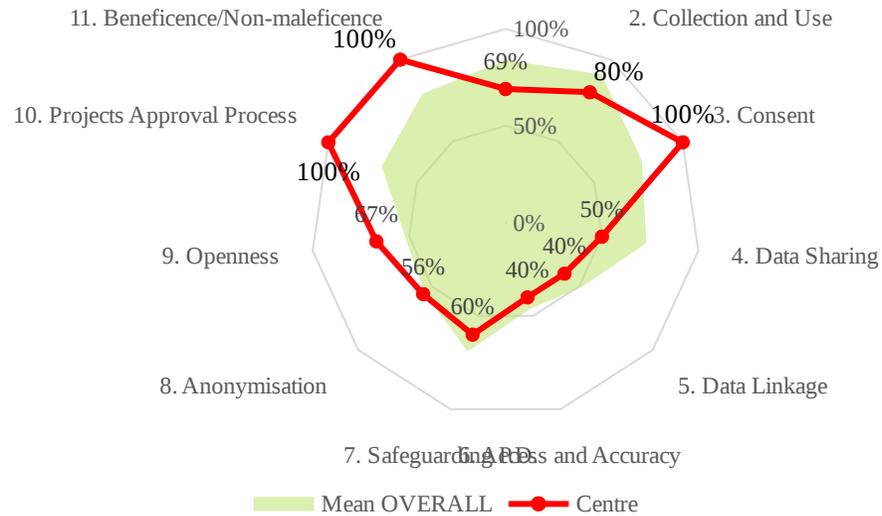
CENTRE "B"

1. Responsibility for P.D.



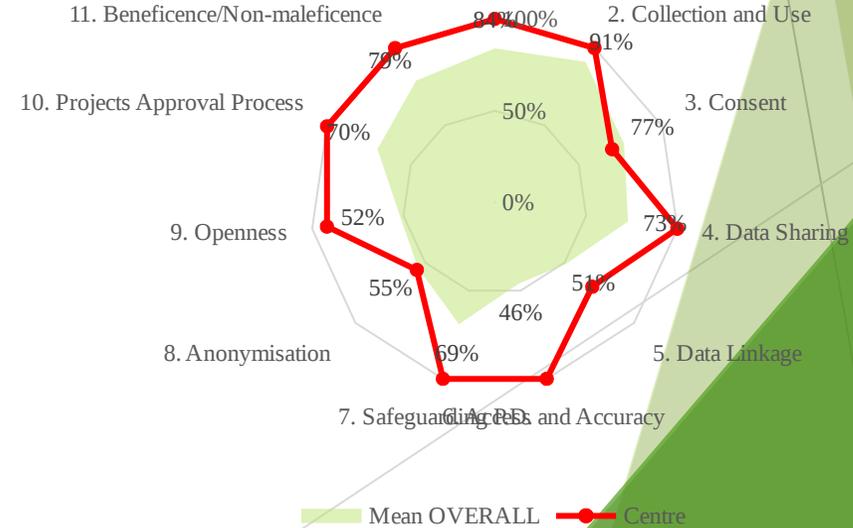
CENTRE "C"

1. Responsibility for P.D.

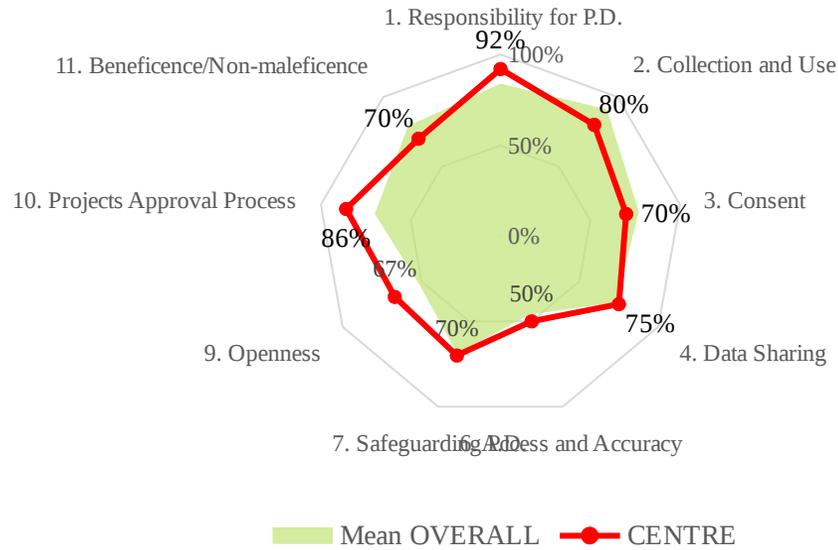


CENTRE "D"

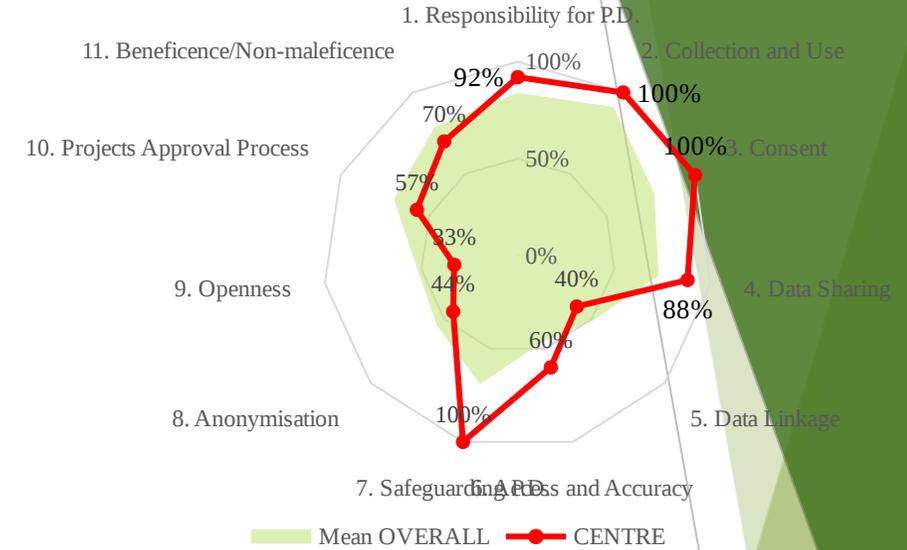
1. Responsibility for P.D.



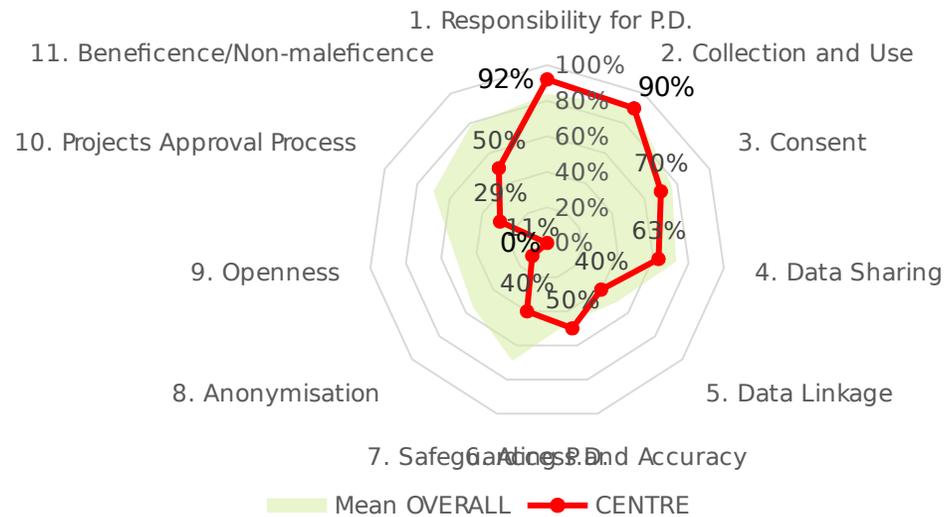
CENTRE "E"



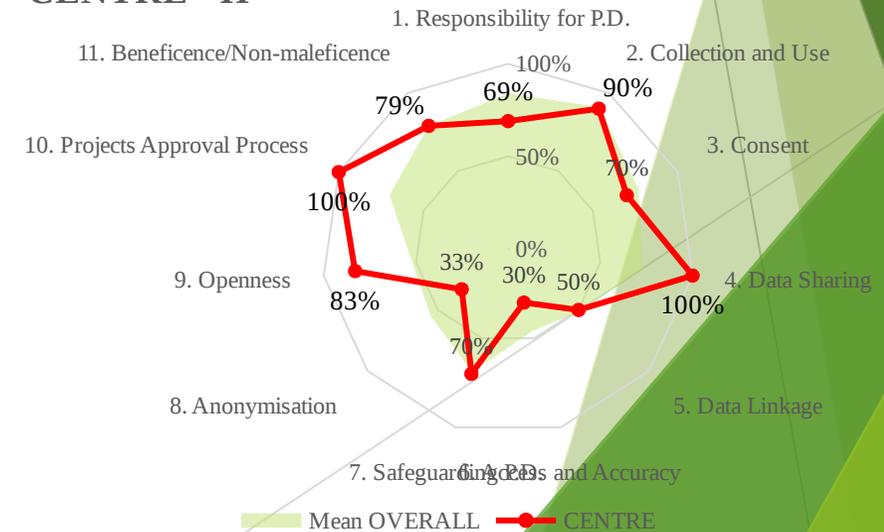
CENTRE "F"



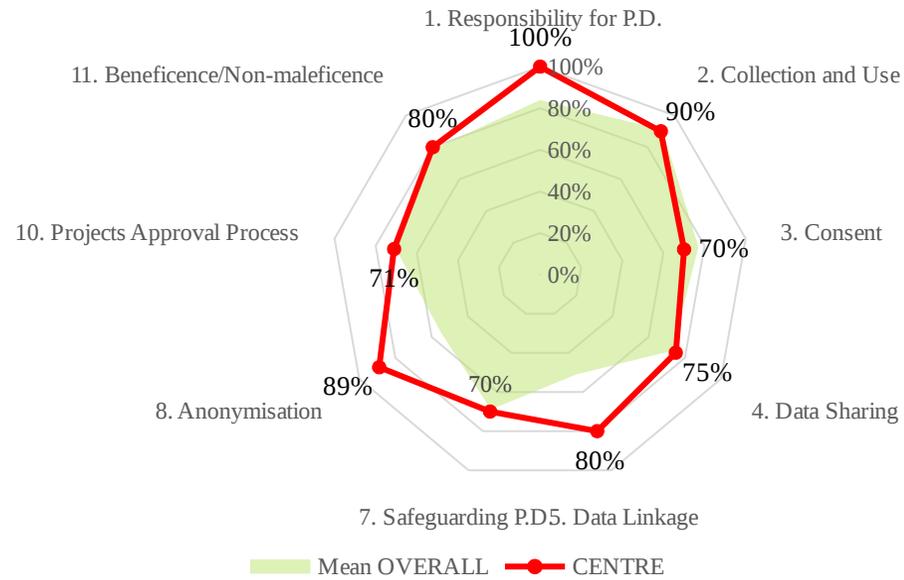
CENTRE "G"



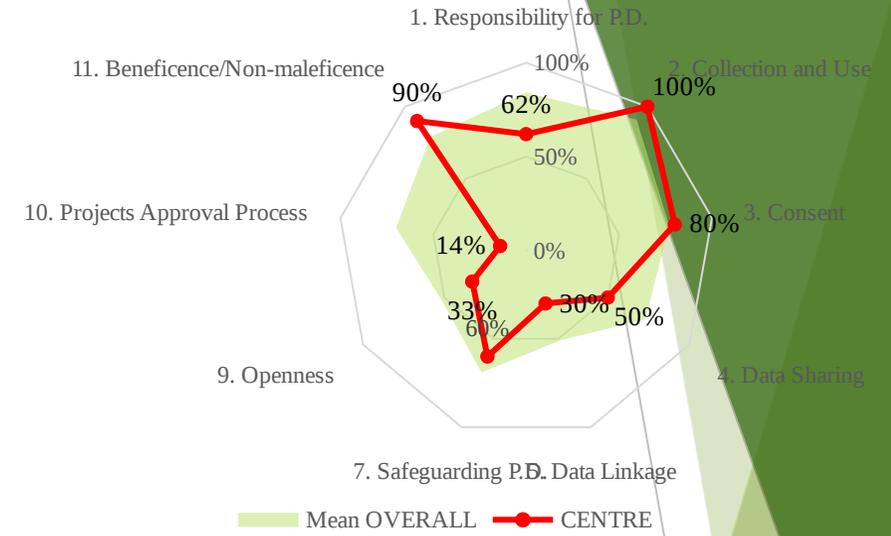
CENTRE "H"



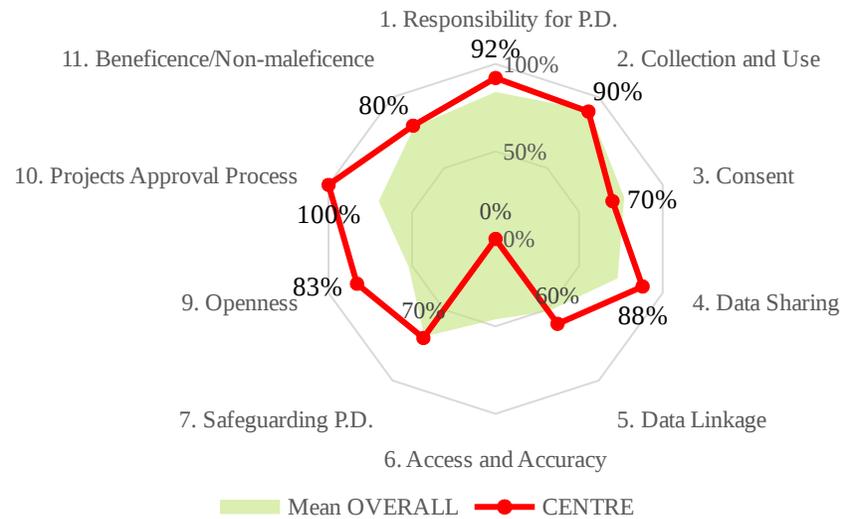
CENTRE "I"



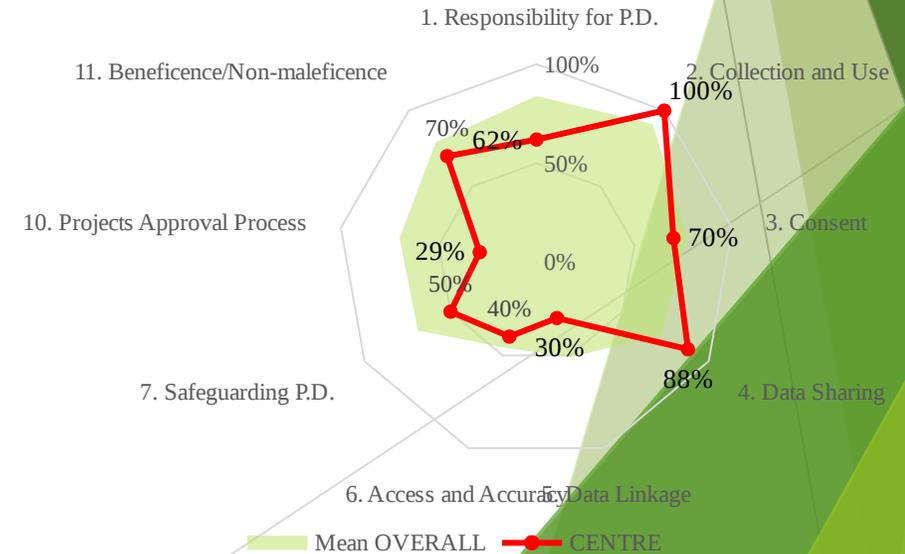
CENTRE "J"



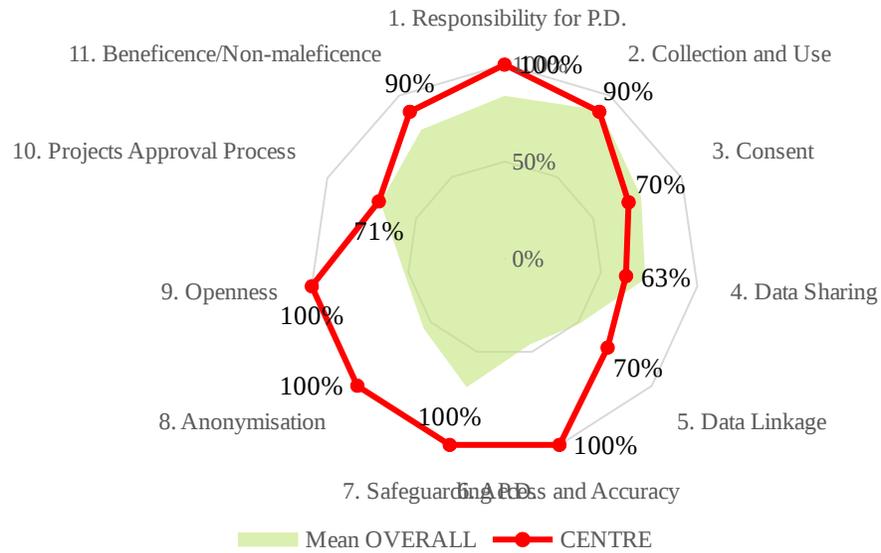
CENTRE "K"



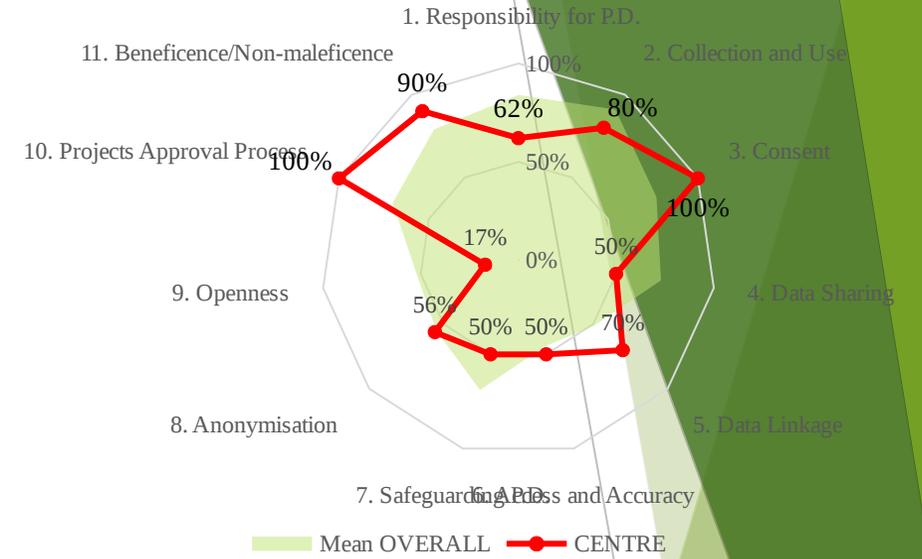
CENTRE "L"



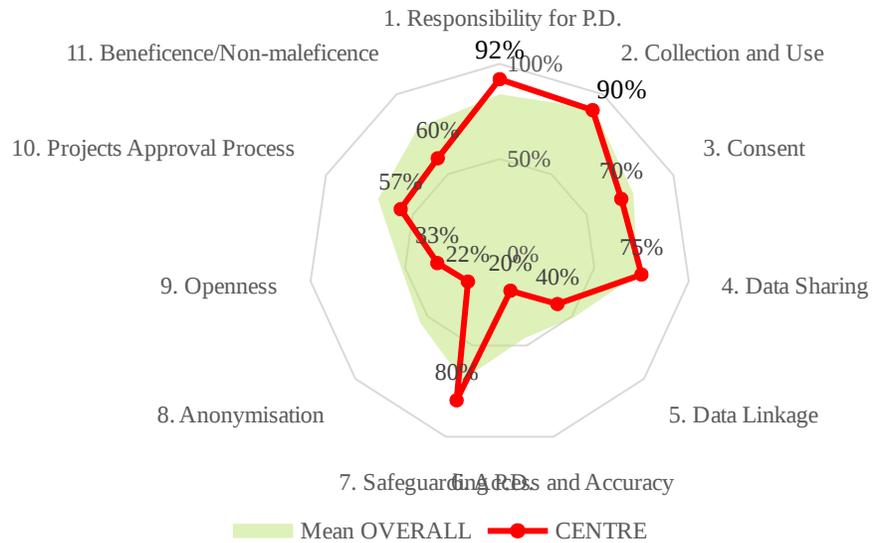
CENTRE "M"



CENTRE "N"



CENTRE "O"



Step 4: Final Report

- ▶ **PEIPA Results** discussed at Privacy and Ethics in Person Meeting (Cyprus, 21st September 2017)
 - ▶ Open section:
 - ▶ to present to BRIDGE-Health participants the PEIPA methodology and results
 - ▶ Open discussion with participants
 - ▶ Close section:
 - ▶ Ad hoc Advisory Panel of Experts meet to fine-tune the analyses of the ethical and privacy issues related to the information systems adopted by the EUBIROD, ECHO and EUROHOPE consortia
- ▶ **Final Report:**
 - ▶ describe the ethical and privacy issues involved in the management of the above information systems and provide results of the Privacy and Ethics Impact and Performance Assessment
 - ▶ provision of objective benchmarks to identify best practices in the implementation of privacy and ethically compliant disease registries/information systems/databases.
- ▶ The WP11 **chapter on Privacy Impact Assessment** will be delivered at Month 30 (end of October 2017).

Any Question?