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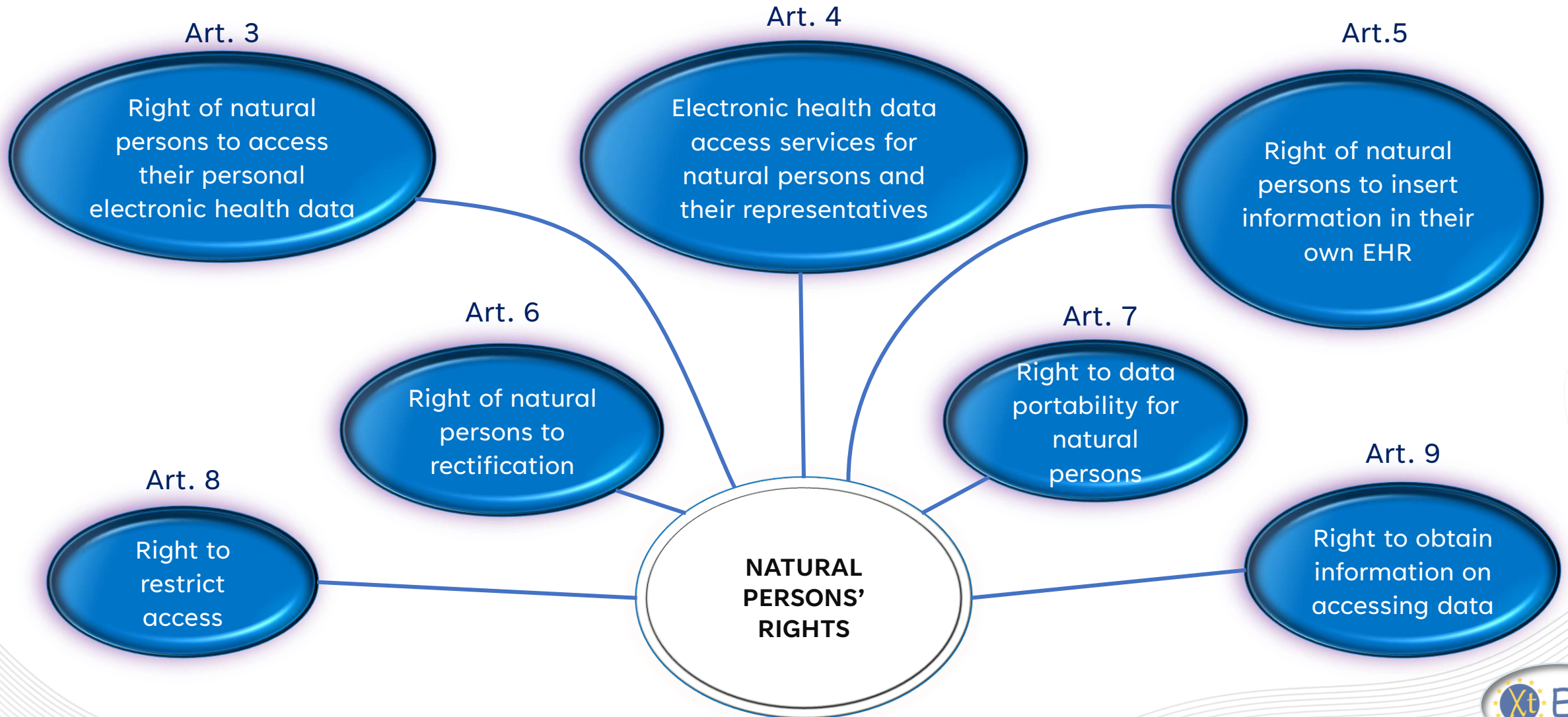
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Patients' rights reflected in the EHDS Regulation

Andreas Christodoulou - Vice President NeHA Cyprus

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



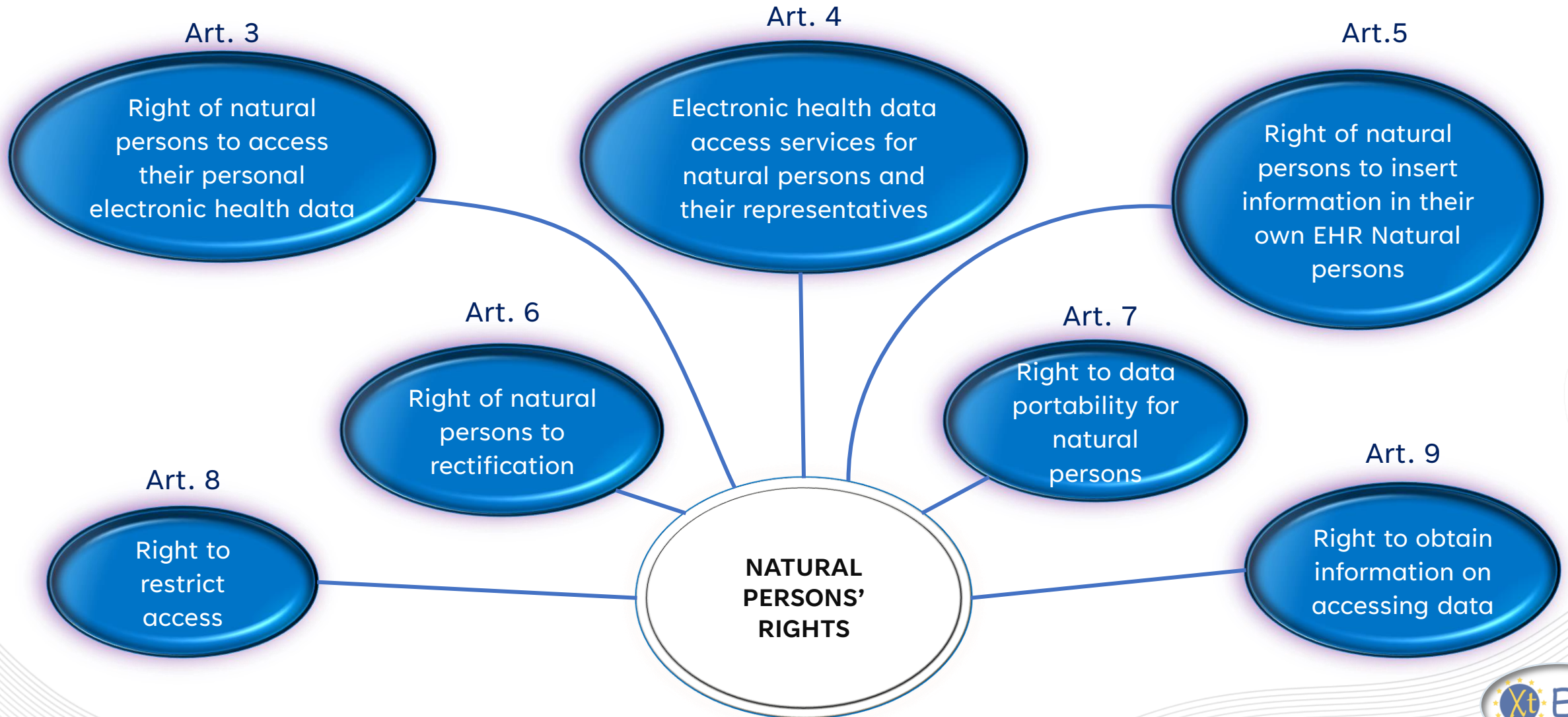
RIGHT OF NATURAL PERSONS TO ACCESS THEIR PERSONAL ELECTRONIC HEALTH DATA

Article 3

Right of natural persons to access their personal electronic health data

1. Natural persons shall have the right to access at least personal electronic health data relating to them that belong to the priority categories referred to in Article 14 and are processed for the provision of healthcare through the electronic health data access services referred to in Article 4. Access shall be provided immediately after the personal electronic health data have been registered in an EHR system, while respecting the need for technological practicability, and shall be provided free of charge and in an easily readable, consolidated and accessible format.
2. Natural persons, or their representatives referred to in Article 4(2), shall have the right to download free of charge an electronic copy of at least the personal electronic health data in the priority categories referred to in Article 14 related to those natural persons, through the electronic health data access services referred to in Article 4, in the European electronic health record exchange format referred to in Article 15.
3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of rights provided for in paragraphs 1 and 2 of this Article, in particular whenever those restrictions are necessary to protect natural persons, on the basis of patient safety and ethical considerations by delaying access to their personal electronic health data for a limited period of time until a health professional is able to properly communicate and explain to the natural persons concerned information that can have a significant impact on their health.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



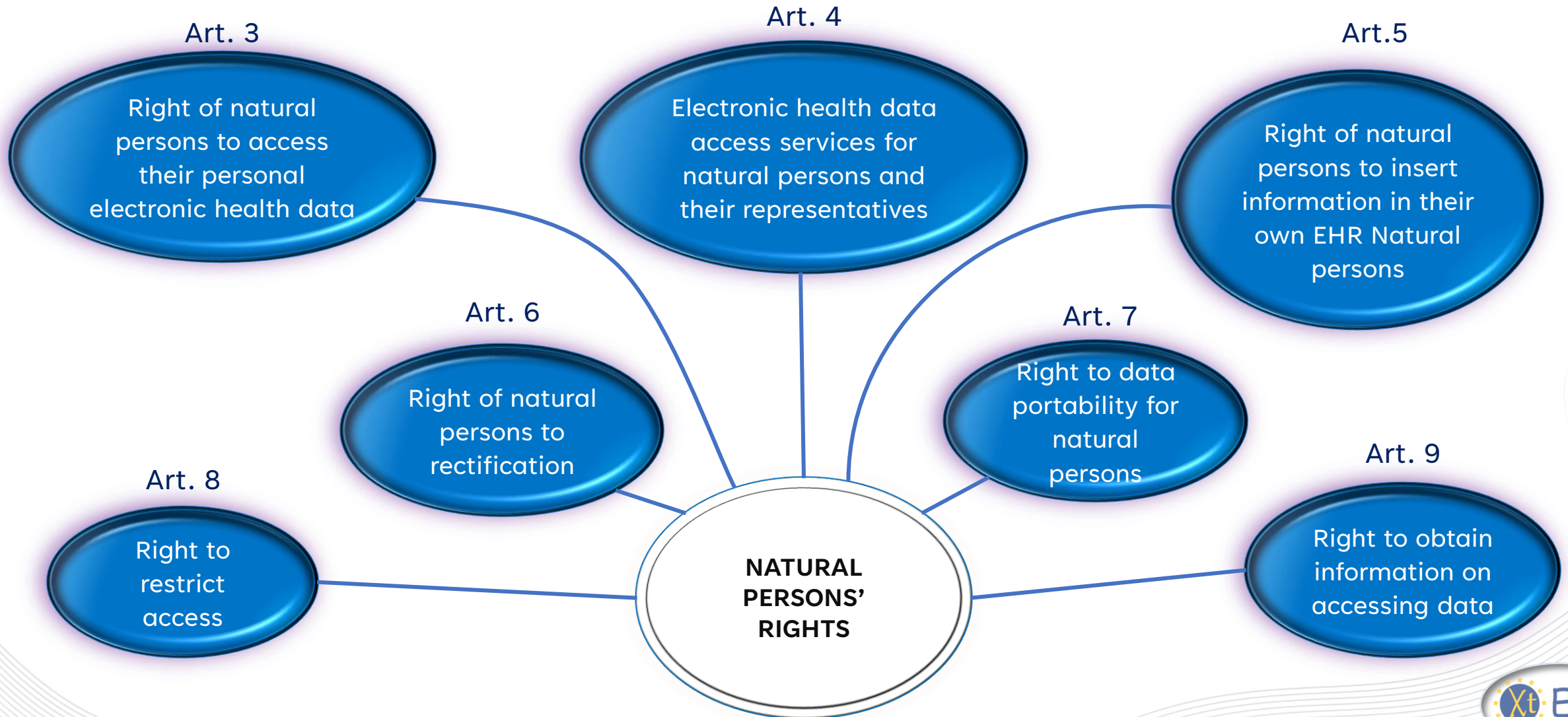
ELECTRONIC HEALTH DATA ACCESS SERVICES FOR NATURAL PERSONS AND THEIR REPRESENTATIVES

Article 4

Electronic health data access services for natural persons and their representatives

1. Member States shall ensure that one or more electronic health data access services at national, regional or local level are established, thereby enabling natural persons to access their personal electronic health data and exercise their rights provided for in Articles 3 and 5 to 10. Such electronic health data access services shall be free of charge for the natural persons and their representatives referred to in paragraph 2 of this Article.
2. Member States shall ensure that one or more proxy services are established as a functionality of electronic health data access services which enables:
 - (a) natural persons to authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf for a limited or unlimited period and, if needed, for a specific purpose only, and to manage those authorisations; and
 - (b) legal representatives of natural persons to access personal electronic health data of those natural persons whose affairs they administer, in accordance with national law.
3. The proxy services referred to in paragraph 2 shall provide authorisations in a transparent and easily understandable way, free of charge, and electronically or on paper. Natural persons and their representatives shall be informed about their authorisation rights, including about how to exercise those rights, and about the authorisation process. The proxy services shall provide an easy complaint mechanism for natural persons.
- ...
5. The electronic health data access services and the proxy services shall be easily accessible for persons with disabilities, vulnerable groups and persons with low digital literacy.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 5

Right of natural persons to insert information in their own EHR.

Natural persons, or their representatives referred to in Article 4(2), shall have the right to insert information in the EHR of those natural persons through electronic health data access services or applications linked to those services as referred to in that Article. That information shall be clearly distinguishable as having been inserted by the natural person or by his or her representative. Natural persons, or their representatives referred to in Article 4(2), shall not be able to directly alter the electronic health data and related information inserted by health professionals.

Article 6

Right of natural persons to rectification

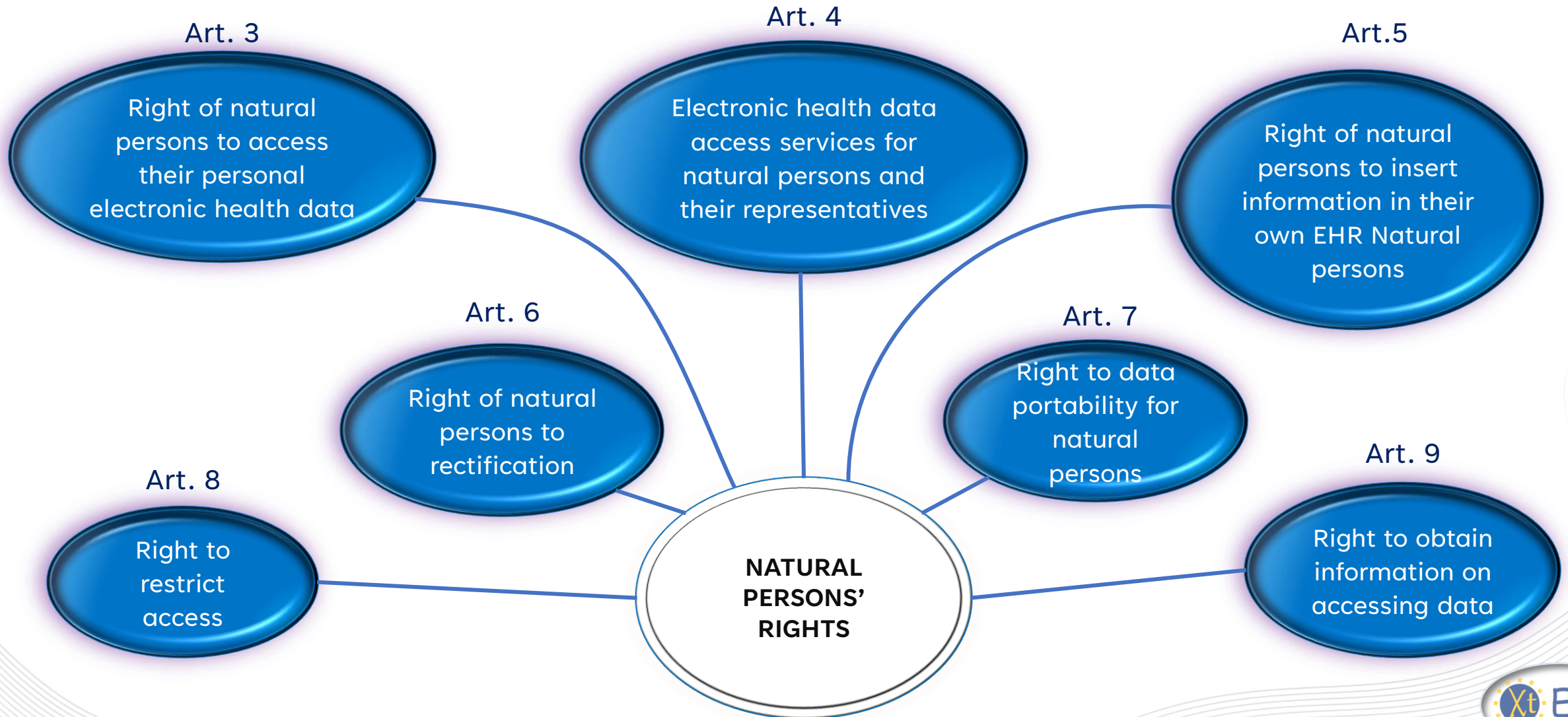
Electronic health data access services referred to in Article 4 shall enable natural persons to easily request online the rectification of their personal electronic health data in accordance with Article 16 of Regulation (EU) 2016/679. Where appropriate, the controller shall verify with a relevant health professional the accuracy of the information provided in the request.

Article 7

Right to data portability for natural persons

1. Natural persons shall have the right to give access to, or to request a healthcare provider to transmit, all or part of their personal electronic health data to another healthcare provider of their choice immediately, free of charge and without hindrance from the healthcare provider or from the manufacturers of the systems used by that healthcare provider.
2. Natural persons shall have the right, where the healthcare providers are located in different Member States, to request the transmission of their personal electronic health data in the European electronic health record exchange format referred to in Article 15 through the cross-border infrastructure referred to in Article 23. The receiving healthcare provider shall accept such data and shall be able to read them.
3. Natural persons shall have the right to request a healthcare provider to transmit a part of their personal electronic health data to a clearly identified recipient in the social security or reimbursement services sector. Such transmission shall be carried out immediately, free of charge and without hindrance from the healthcare provider or from the manufacturers of the systems used by that healthcare provider, and shall be one-way only.
4. Where natural persons have downloaded an electronic copy of their priority categories of personal electronic health data in accordance with Article 3(2) they shall be able to transmit those data to healthcare providers of their choice in the European electronic health record exchange format referred to in Article 15. The receiving healthcare provider shall accept such data and be able to read them, as applicable.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 8

Right to restrict access

Natural persons shall have the right to restrict the access of health professionals and healthcare providers to all or parts of their personal electronic health data as referred to in Article 3. When exercising the right referred to in the first paragraph, natural persons shall be made aware that restricting access might impact the provision of healthcare to them. The fact that a natural person has restricted access under the first paragraph shall not be visible to healthcare providers. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.

Article 9

Right to obtain information on accessing data

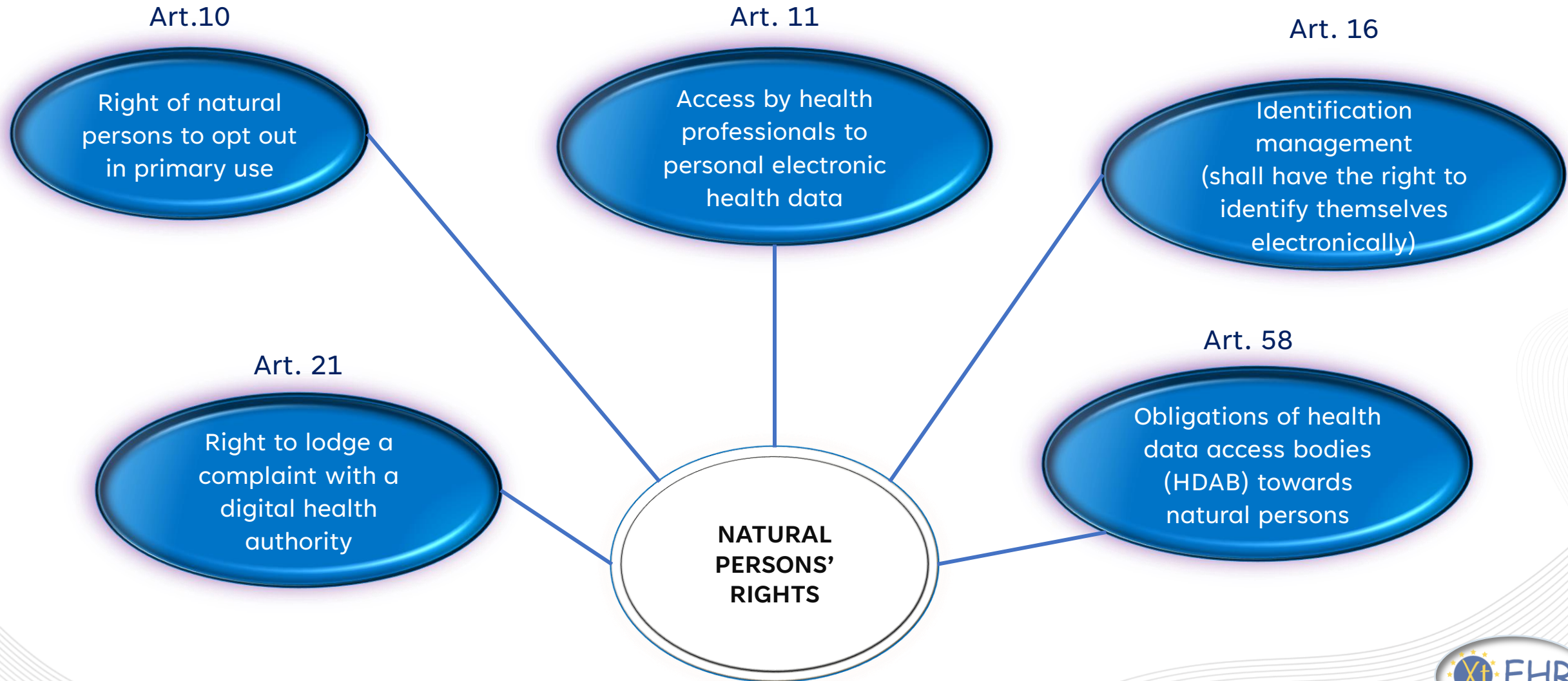
1. Natural persons shall have the right to obtain information, including through automatic notifications, on any access to their personal electronic health data through the health professional access service obtained in the context of healthcare, including access provided in accordance with Article 11(5).

2. The information referred to in paragraph 1 shall be provided free of charge and without delay through electronic health data access services and shall be available for at least three years from each date of access to the data. That information shall include at least the following:

- (a) information on the healthcare provider or other individuals who accessed the personal electronic health data;
- (b) the date and time of access;
- (c) which personal electronic health data were accessed.

3. Member States may provide for restrictions to the right referred to in paragraph 1 in exceptional circumstances, where there are factual indications that disclosure would endanger the vital interests or rights of the health professional or the care of the natural person.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 10

Right of natural persons to opt out in primary use

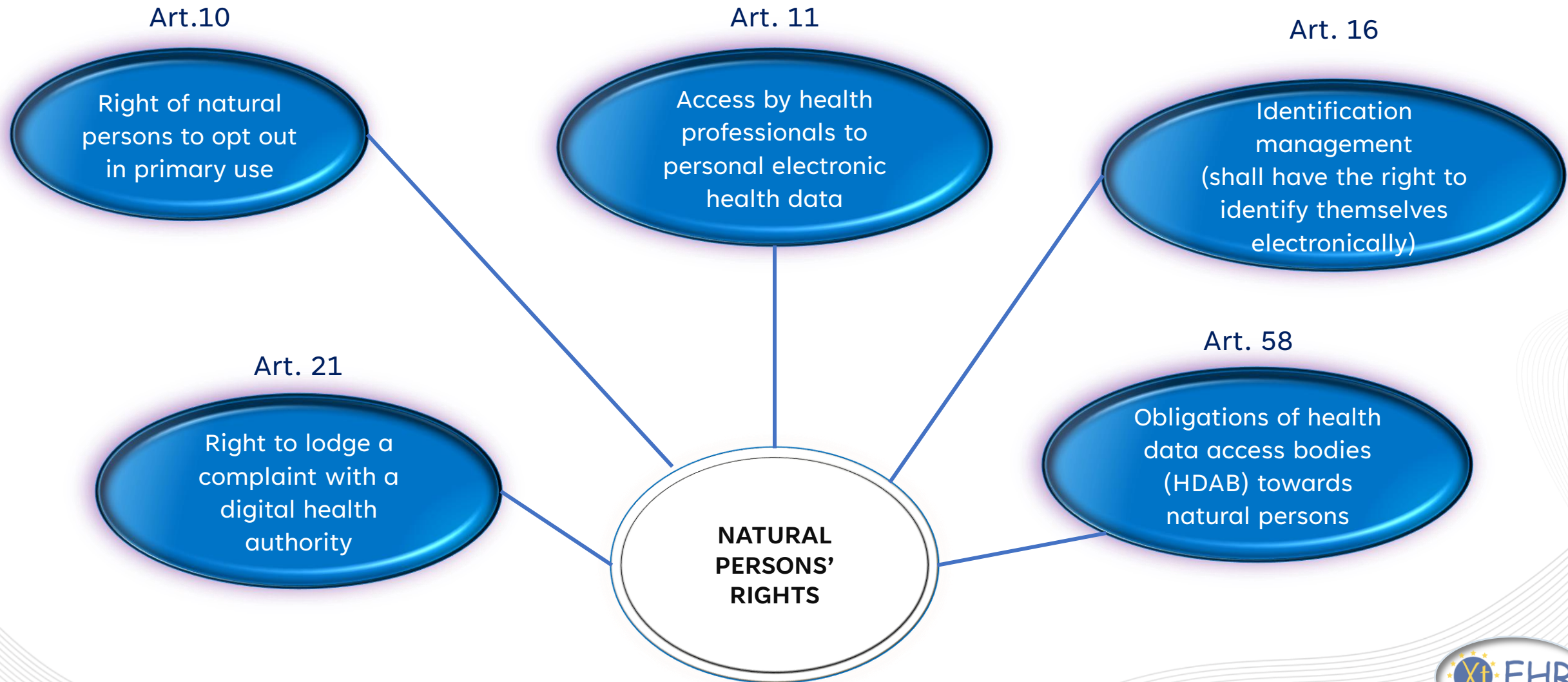
1. Member States' laws may provide that natural persons have the right to opt out from the access to their personal electronic health data registered in an EHR system through the electronic health data access services referred to in Articles 4 and 12. In such cases, Member States shall ensure that the exercise of that right is reversible.
2. If a Member State provides for a right referred to in paragraph 1 of this Article, it shall establish the rules and specific safeguards regarding the opt-out mechanism. In particular, Member States may provide for a healthcare provider or health professional to be able to get access to the personal electronic health data in cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person as referred to in Article 9(2), point (c), of Regulation (EU) 2016/679, even if the patient has exercised the right to opt out in primary use.

Article 11

Access by health professionals to personal electronic health data

1. Where health professionals process data in an electronic format, they shall have access to the relevant and necessary personal electronic health data of natural persons under their treatment through the health professional access services referred to in Article 12, irrespective of the Member State of affiliation and the Member State of treatment.
2. Where the Member State of affiliation of the natural person under treatment and the Member State of treatment of such natural person differ, cross-border access to the personal electronic health data of the natural person under treatment shall be provided through the cross-border infrastructure referred to in Article 23.
- ...
5. Where access to personal electronic health data has been restricted by a natural person pursuant to Article 8, the healthcare provider or health professional shall not be informed of the restricted content of those data. By way of derogation from the first paragraph of Article 8, where necessary in order to protect the vital interests of the data subject, the healthcare provider or health professional may be granted access to the restricted electronic health data. Such cases shall be logged in a clear and understandable format and shall be easily accessible for the data subject. Member States may provide for additional safeguards.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



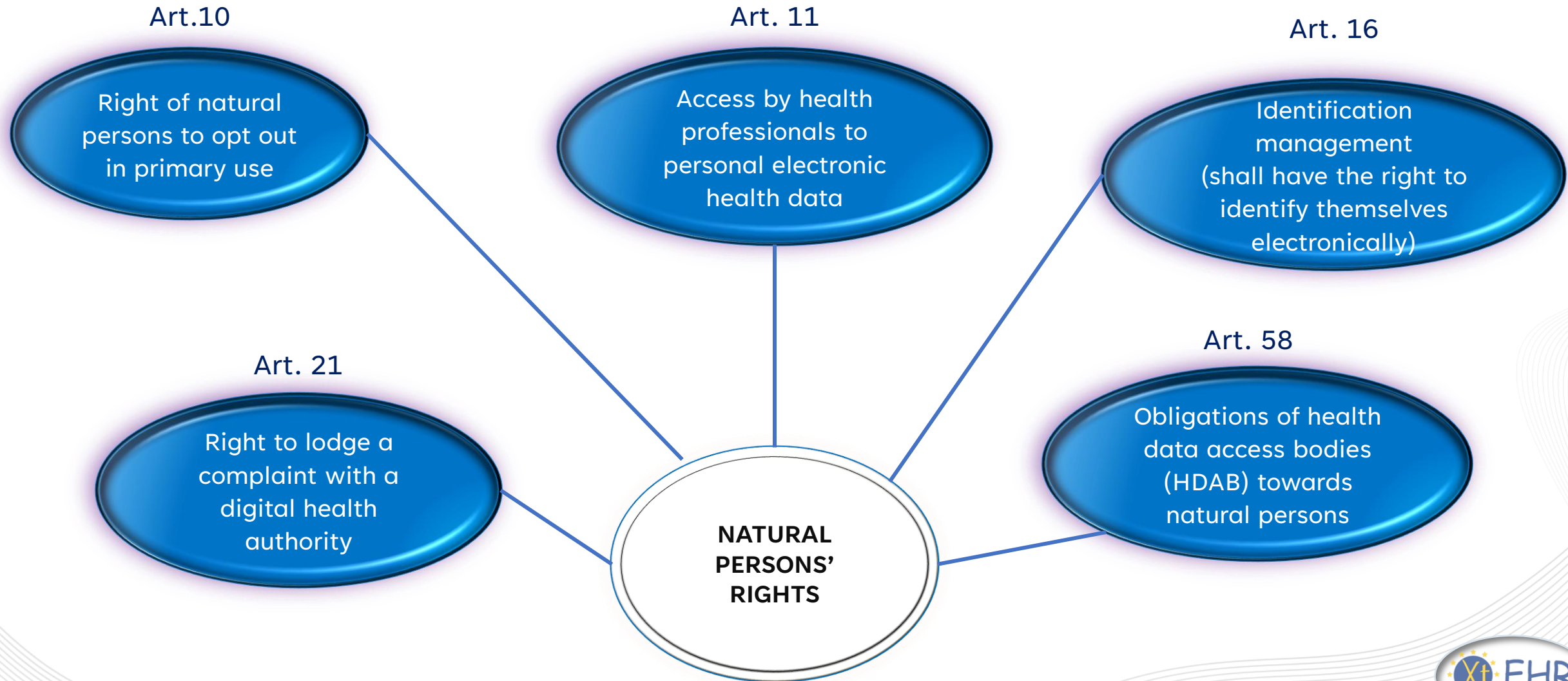
NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 16

Identification management

1. Where natural persons use electronic health data access services referred to in Article 4, those natural persons shall have the right to identify themselves electronically using any electronic identification means which are recognised pursuant to Article 6 of Regulation (EU) No 910/2014. Member States may provide complementary mechanisms to ensure appropriate identity matching in cross border situations.
2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014. That mechanism shall facilitate the transferability of personal electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 98(2).
3. The Commission, in cooperation with Member States, shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border infrastructure referred to in Article 23.
4. The Member States' competent authorities and the Commission shall implement the interoperable, cross-border identification and authentication mechanism at Member State and Union level, respectively.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



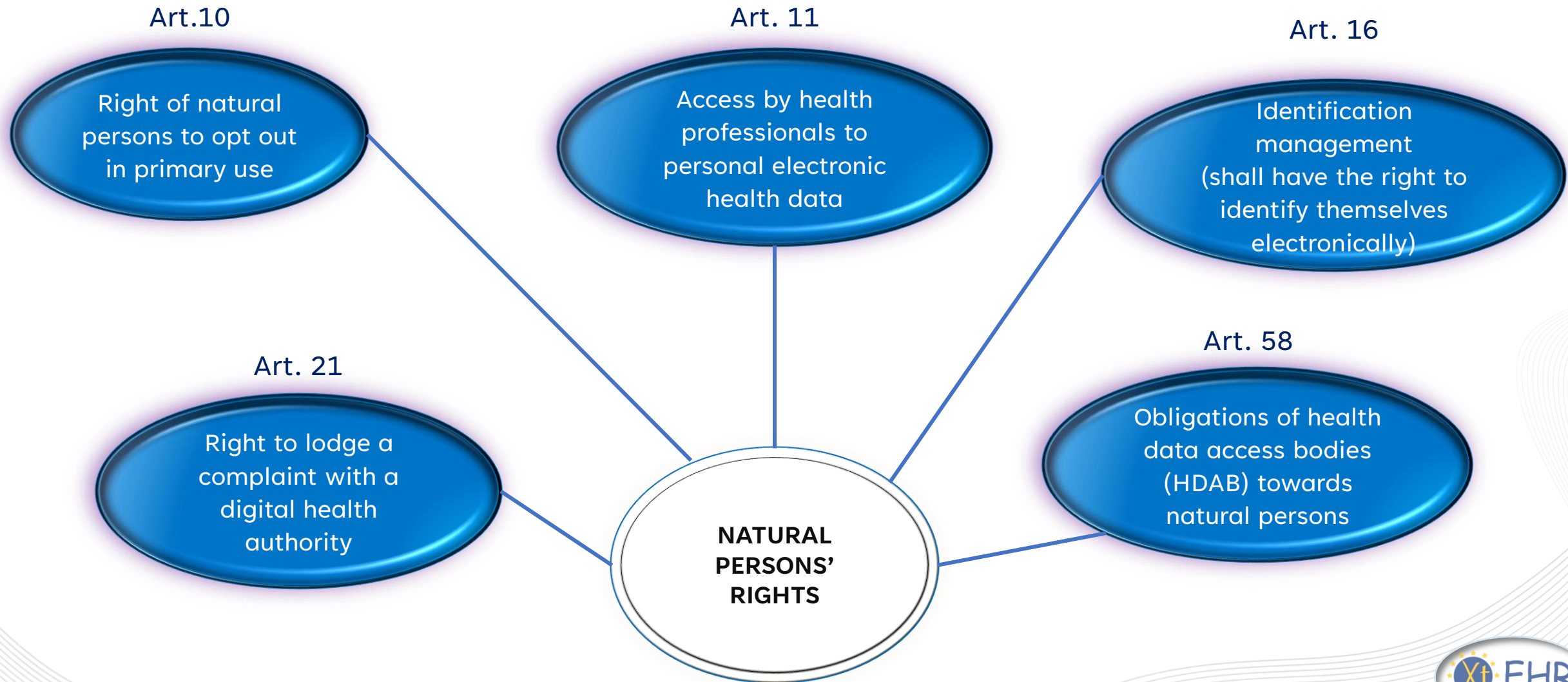
NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 21

Right to lodge a complaint with a digital health authority

1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint in relation to the provisions laid down in this Chapter, individually or, where relevant, collectively, with the competent digital health authority, provided that their rights or interests are negatively affected.
2. Where the complaint concerns the rights of natural persons pursuant to Articles 3 and 5 to 10 of this Regulation, the digital health authority shall transmit the complaint to the competent supervisory authorities under Regulation (EU) 2016/679. The digital health authority shall provide the necessary information at its disposal to the competent supervisory authority under Regulation (EU) 2016/679 in order to facilitate the assessment and investigation of the complaint.
3. The competent digital health authority with which the complaint has been lodged shall inform, in accordance with national law, the complainant of the progress made in dealing with the complaint, of the decision taken on the complaint, of any referral of the complaint to the competent supervisory authority under Regulation (EU) 2016/679 and, in cases of such a referral, that that supervisory authority is, from that moment on, to be the sole point of contact for the complainant in that matter.
4. Digital health authorities in the Member States concerned shall cooperate to handle and resolve complaints related to cross-border exchange of and access to personal electronic health data, including by exchanging all relevant information by electronic means, without undue delay.
5. Digital health authorities shall facilitate the submission of complaints and provide easily accessible tools for the submission of complaints.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS



NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 58

Obligations of health data access bodies towards natural persons

1. Health data access bodies shall make information on the conditions under which electronic health data are made available for secondary use publicly available, easily searchable through electronic means and accessible for natural persons. That information shall cover the following:
 - a. the legal basis under which access to electronic health data is granted to the health data user
 - b. the technical and organisational measures taken to protect the rights of natural persons
 - c. the applicable rights of natural persons in relation to secondary use
 - d. the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679
 - e. the identity and the contact details of the health data access body
 - f. who has been granted access to datasets of electronic health data and to which datasets they were granted access and details of the data permit regarding the purposes for processing such data as referred to in Article 53(1)
 - g. the results or outcomes of the projects for which the electronic health data were used
2. If a Member State has provided for the right to opt out pursuant to Article 71 to be exercised through the health data access bodies, the relevant health data access bodies shall provide public information about the procedure to opt out and facilitate the exercise of that right.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Art. 71

Right to opt out from the processing of personal electronic health data for secondary use

Art. 81

Right to lodge a complaint with a health data access body (HDAB)

Art. 84

Digital health literacy and digital health access – Maturity Level

Art. 100

Right to receive compensation (has suffered material or non-material damage)

Art. 101

Representation of a natural person when ones rights have been infringed

**NATURAL
PERSONS'
RIGHTS**

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 71

Right to opt out from the processing of personal electronic health data for secondary use

1. Natural persons shall have the right to opt out at any time, and without providing any reason, from the processing of personal electronic health data relating to them for secondary use under this Regulation. The exercise of that right shall be reversible.

2. Member States shall provide for an accessible and easily understandable opt-out mechanism to exercise the right established in paragraph 1, whereby natural persons may explicitly state that they do not wish to have their personal electronic health data processed for secondary use.

3. Once natural persons have exercised the right to opt out, and where personal electronic health data relating to them can be identified in a dataset, personal electronic health data relating to those natural persons shall not be made available or otherwise processed pursuant to data permits issued under Article 68 or health data requests under Article 69 approved after the natural person has exercised the right to opt out.

The first subparagraph of this paragraph shall not affect the processing for secondary use of personal electronic health data relating to those natural persons pursuant to data permits or health data requests that were issued or approved before the natural persons exercised their right to opt out.

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NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 81

Right to lodge a complaint with a health data access body

1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint in relation to the provisions laid down in this Chapter, individually or, where relevant, collectively, with a health data access body, provided that their rights or interests are negatively affected.
2. The health data access body with which the complaint has been lodged shall inform the complainant of the progress made in dealing with the complaint and of the decision taken on the complaint.
3. Health data access bodies shall provide easily accessible tools for the submission of complaints.
4. Where the complaint concerns the rights of natural persons pursuant to Article 71 of this Regulation, the complaint shall be transmitted to the competent supervisory authority under Regulation (EU) 2016/679. The relevant health data access body shall provide the necessary information at its disposal to that supervisory authority under Regulation (EU) 2016/679 in order to facilitate the assessment and investigation of the complaint.

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NATURAL PERSONS' RIGHTS

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 84

Digital health literacy and digital health access

1. Member States shall promote and support digital health literacy and the development of relevant competences and skills for patients. The Commission shall support Member States in this regard. Awareness-raising campaigns or programmes shall aim, in particular, to inform patients and the public at large about primary use and secondary use in the framework of the EHDS, including the rights arising from it, as well as the advantages, risks and potential gains for science and society of primary use and secondary use.
2. The awareness-raising campaigns and programmes referred to in paragraph 1 shall be tailored to the needs of specific groups and shall be developed, reviewed and, where necessary, updated.
3. Member States shall promote access to the infrastructure necessary for the effective management of natural persons' electronic health data, both for primary use and secondary use.

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Art. 71

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NATURAL PERSONS' RIGHTS

NATURAL PERSON'S RIGHTS IN ARTICLES OF THE EHDS

Article 100

Right to receive compensation

Any natural or legal person that has suffered material or non-material damage as a result of an infringement of this Regulation shall have the **right to receive compensation**, in accordance with Union and national law.

Article 101

Representation of a natural person

Where a natural person considers that his or her rights under this Regulation have been infringed, he or she shall have the **right to mandate a not-for-profit body, organisation or association**, constituted in accordance with national law, having statutory public interest objectives and active in the field of the protection of personal data, to lodge a complaint on his or her behalf or to exercise the rights referred to in Articles 21 and 81.



**Thank you
for your attention**



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