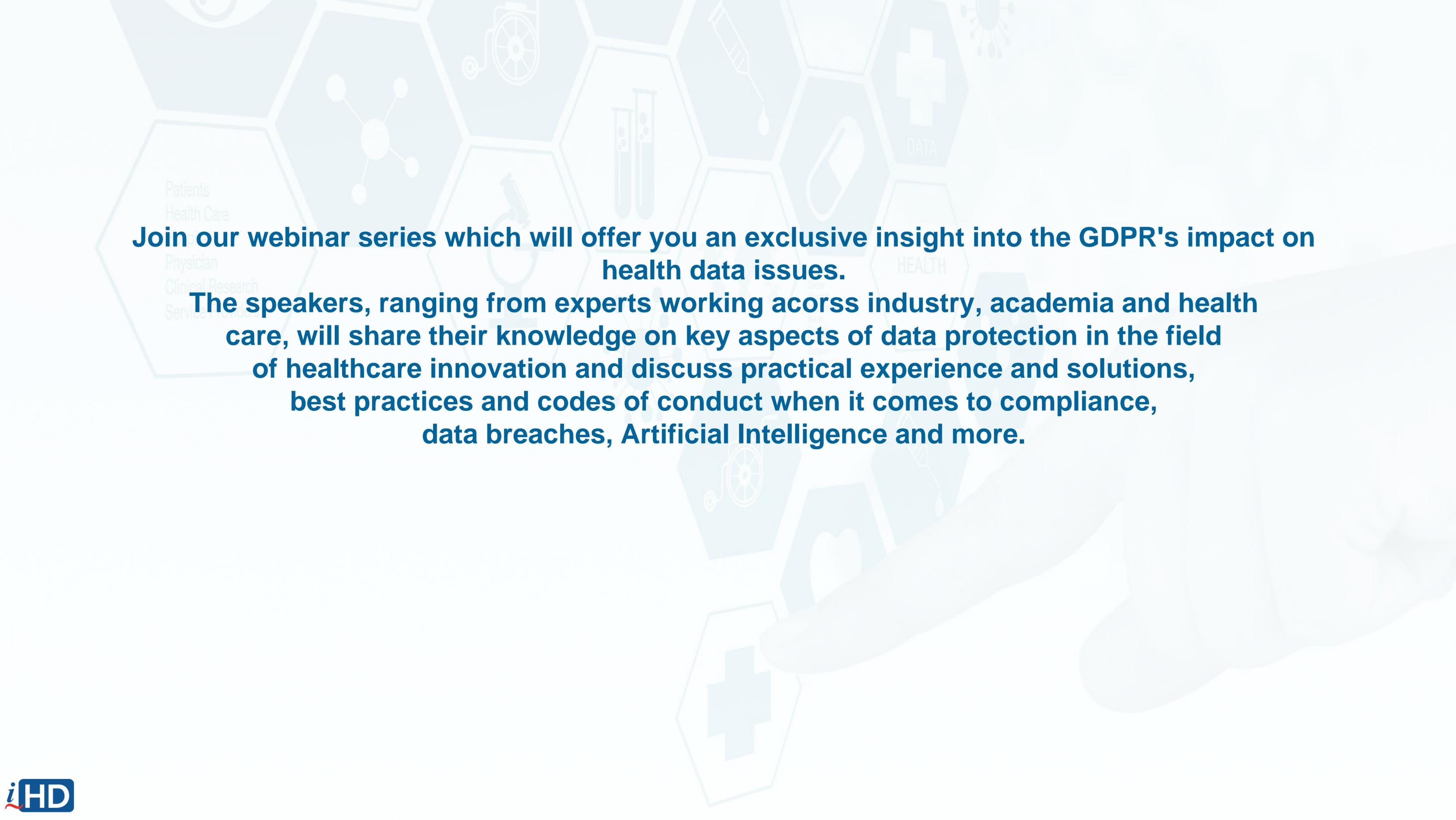




The European Institute
for Innovation through
Health Data

**i~HD webinar series 2021:
GDPR for tomorrow's health data-driven innovation**

How to successfully harness GDPR to meet health data reuse challenges and realise opportunities as the number and scale of health data and research infrastructures across Europe grows.



Join our webinar series which will offer you an exclusive insight into the GDPR's impact on health data issues.

The speakers, ranging from experts working across industry, academia and health care, will share their knowledge on key aspects of data protection in the field of healthcare innovation and discuss practical experience and solutions, best practices and codes of conduct when it comes to compliance, data breaches, Artificial Intelligence and more.

What can you learn from our GDPR Programme?

- How does the GDPR impact on the collection, storage and uses of health data?
- What are the steps required to develop a GDPR-compliant health data pipeline?
- How should you conduct a Data Protection Impact Assessment?
- What safeguards does the GDPR require when capturing, analysing or sharing data?
- What are good practices when wording consent forms, transparency notices?
- What code of conduct should your staff adopt when working with health data?
- How can you protect against data breaches and their stringent penalties?
- What are the best methods to anonymise health data?
- How to develop AI complying with the GDPR, MDR, and the new AI Regulation?

Who should attend?

- ✓ Patient organisations
- ✓ Health care providers
- ✓ Pharma & life sciences
- ✓ Health ICT and data driven industry
- ✓ Health & data strategy organisations
- ✓ Health policy makers & funders
- ✓ Academia & research centres
- ✓ Standards & certification bodies

Our 2021 webinar programme

Topic	Date
How does the GDPR apply to health data?	16/09/2021
Setting up a GDPR-compliant data collection and processing pipeline	28/09/2021
Patient and participate consent, transparency notices and data subject rights	08/10/2021
Data protection safeguards, threats and breaches	15/10/2021
Anonymisation and pseudonymisation	15/11/2021
Regulatory compliance for AI development	23/11/2021
Ask the GDPR experts!	09/12/2021

Webinar 1: How does the GDPR apply to health data?

To which organisations, to which kinds of health data and for what processing purposes does the GDPR apply, how does it constrain what do you are permitted to do and how can you ensure that you comply with it?

Date: 16/09/2021

Time: 14.00 CEST

Duration: 2 hours

Topics covered include: Why the GDPR was introduced (its purpose), to whom and what it applies to. The GDPR principles and how these impact on the main data flows when collecting and analysing health data through apps, wearables, clinical systems and research systems. Practical adoption and compliance steps (e.g. what is a DPIA, what legal bases are often used in different situations). Boundary conditions: data minimisation, use that is consistent with the legal basis, catering for withdrawal of consent. Good practices that should be adopted: transparency, information security measures, codes of conduct. An introduction to anonymisation and pseudonymisation. If COVID-19 has changed the expectation landscape. Q&A from the audience.

Webinar 2: Setting up a GDPR-compliant data collection and processing pipeline

What are the GDPR compliance steps and specifications that should be adopted when developing and innovation or a research study that collect, processes, retains, analyses and possibly shares health data from patients, citizens, or research data subjects?

Date: 28/09/2021

Time: 14.00 CEST

Duration: 2 hours

Topics covered include: The GDPR legal basis options, strengths and limitations of each, how to choose the most appropriate one for the anticipated needs. What approvals are usually needed in the context of conducting research or data sharing, what documentation evidence do these require, what are the main issues that ethics committees insist on, how to successfully complete a European Commission grant proposal ethics section. Formalising the required documentation of the intended data sources, data flows, data items and processing needs, issues with adopting data minimisation in research. Conducting a Data Protection Impact Assessment (DPIA), and using this to determine the relevant safeguards to commit to, and then adopt. Q&A from the audience.

Webinar 3: Patient and participate consent, transparency notices and data subject rights

Which data processing activities need formal permission from patients and research data subjects, how consent forms and transparency notices should be worded and how meet the obligations of data subject right such as withdrawal.

Date: 08/10/2021

Time: 14.00 CEST

Duration: 2 hours

Topics covered include: How to determine and then specify the data collection, storage, analysis and reuse permissions you need to request from participants, and then how to word patient choices, consent forms and transparency notices in ways that assure those permission whilst being understandable and clear. What data subject access rights does the GDPR committee you to, and how to comply with the right to portability. Handling participant withdrawal: scenarios and obligations, transparency and feedback. How to re-approach patients/users for additional permissions downstream, for example if new data use opportunities arise. Q&A from the audience.

Webinar 4: Data protection safeguards, threats and breaches

How to determine what information security safeguards are appropriate for the intended data, data flows, processing and risks within the data pipeline, how best to apply and combine them to assure appropriate levels of protection, and what to do if there is a data breach.

Date: 15/10/2021

Time: 14.00 CEST

Duration: 2 hours

Topics covered include: Leveraging the originally-conducted Data Protection Impact Assessment to determine the requirements for organisational, physical and technical safeguards. The main information security safeguards that should be adopted by an organisation, and the additional safeguards that should be adopted for information sharing and federated querying. Developing a data code of conduct for staff, inducting and monitoring staff, demonstrating organisational compliance. The principal threats potential errors, and how to ensure adequate protection against them. Handling a data breach including your legal obligations. Q&A from the audience.

Webinar 5: Anonymisation and pseudonymisation

One important protection of data is anonymisation, potentially making the data non-personal and therefore no longer within the scope of the GDPR, but this is challenging to achieve robustly without making the data much less usable.

Date: 15/11/2021

Time: 14.00 CEST

Duration: 2 hours

Topics covered include: Why anonymisation is useful with regard to GDPR and data protection, and how this aids compliance with data minimisation. Principles and main methods for anonymisation, examples of data transformation rules that can be applied. Tools for implementing anonymisation rules e.g. ARX. Disclosure controls that need to be adopted on top of data anonymisation. Why is pseudonymisation useful, principles, the main methods adopted, protecting pseudonymisation keys, managing longitudinal linkage. Data transfers or data access outside the EU. Contrasting GDPR (Europe) and HIPAA (US) regarding de-identification standards. Q&A from the audience.

Webinar 6: Regulatory compliance for AI development

The combined implications for artificial intelligence development within the GDPR, the Medical Device Regulation and the forthcoming EU Regulation on AI.

Date: 23/11/2021

Time: 14.00 CEST

Duration: 2 hours

Topics covered include: Enabling permitted access to big data resources that are often needed to develop and validate AI algorithms, knowing and reducing bias in AI development. The requirements of the Medical Device Regulation on the development and use of AI, and how to ensure compliance, what evidence of transparency, trustworthiness and safety a healthcare provider or health region may require before it will adopt an AI solution. How the new EU Regulation on AI introduces a robust and risk-based assessment and compliance approach: how to be AI-Regulation-ready. Q&A from the audience.

Webinar 7: Ask the GDPR experts!

An opportunity for our past webinar participants to pose their specific challenges, obstacles or new ambitions to our panel of GDPR experts for advice - a problem clinic!

Date: 09/12/2021

Time: 14.00 CEST

Duration: 2 hours

People who have participated in one or more past webinars in this programme will be eligible to submit a question (in advance) to our panel. This may be about how to tackle a specific challenge, or how best to leverage a new data use opportunity in compliance with the GDPR. The panel expert answers will provide a specific response to the question in its context, plus generalised learning points from that situation that may be relevant others in the audience. Questions arising from any of the previous webinars in the programme can be considered.

Contact - registration - fee

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Registration: possible from 15/06/2021

Fee:	• Webinar 1	free
	• One webinar	150 euro
	• All webinars	600 euro