



Broad concept of digital reporting in an accreditation body

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IT in accredited laboratories



Already the grand old **ISO 17025:2005** did address IT issues:

4.12 ...NOTE Records may be in any media, such as hard copy or **electronic media**.

.. have procedures to protect and back-up records **stored electronically**

5.4.7.2 **When computers or automated equipment** are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that ...**computer software** developed by the user is documented in sufficient detail and is **suitably validated** as being adequate for use; ... and procedures are established and implemented for **protecting the data**...

IT in accredited laboratories



And finally:

5.10.7 Electronic transmission of results: In the case of **transmission** of test or calibration results by **telephone, telex, facsimile or other electronic or electromagnetic means**, the requirements of this International Standard shall be met (see also 5.4.7).

IT in accredited laboratories



The brand-new **ISO 17025:2017** address IT issues in a more mature language:

6.4.1 The laboratory shall have access to **equipment** (including, but not limited to, measuring instruments, **software**,...

7.8 (Reporting): NOTE 2 — Reports can be issued as hard copies **or by electronic means**, provided that the requirements of this document are met.

7.11 (Control of data and information management): ...The laboratory information management system(s) used for the **collection, processing, recording, reporting, storage or retrieval of data**...shall be validated [*No “When used” in this clause*]

...NOTE 1 — In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems.

Examples for electronic reporting in accredited labs in DANAK

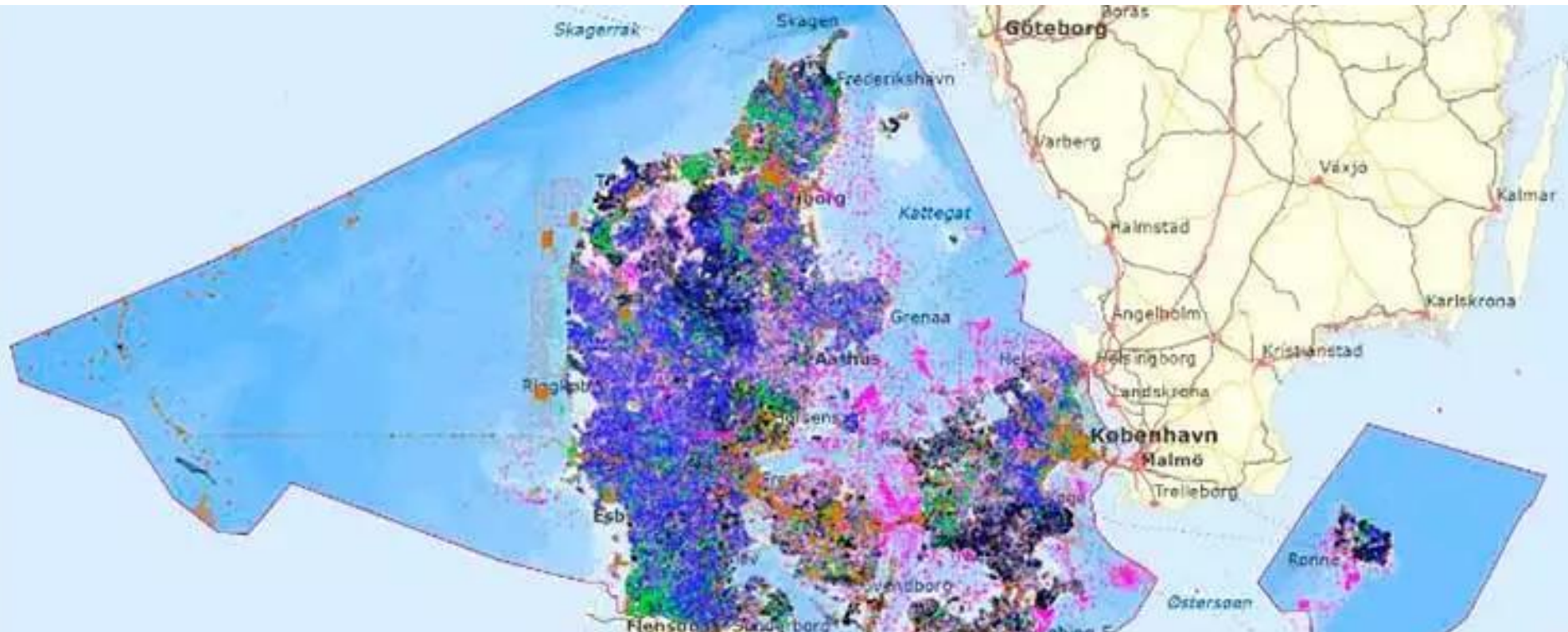


- Reports as pdf files transmitted by email (2000-).
- Data reported as a separate file of data eventually accompanied by a formal report (e.g. calibration of multi-range/multi-frequency instruments or environmental test data) (2000-).
- Customers logging in to collect their calibration certificate electronically in pdf format since middle 2000-2010.
- Medical examination both requests and reporting (same period)

Jupiter



- 418.000 drillings in Denmark (42.933 km²)
- Ground water and drinking water reservoirs
- Laboratories enter data electronically according to an established protocol (data at least since 2005).



WHO IS MEDCOM?

MedCom supports **cooperation and digital communication** between different parts of the Danish healthcare sector in order to minimise medical errors and ensure the best possible service for patients.

MedCom works closely with the different parts of the **healthcare sector and IT vendors** to find the most effective solutions.

MedCom ensures that specialised IT systems can **exchange** the necessary health-related information in a secure environment when a patient's course of treatment involves contact with more than one part of the healthcare sector.

MedCom standards



MedCom's standards include **EDI letters** for message-based data exchange and **XML letters** for message-based or online data exchange.

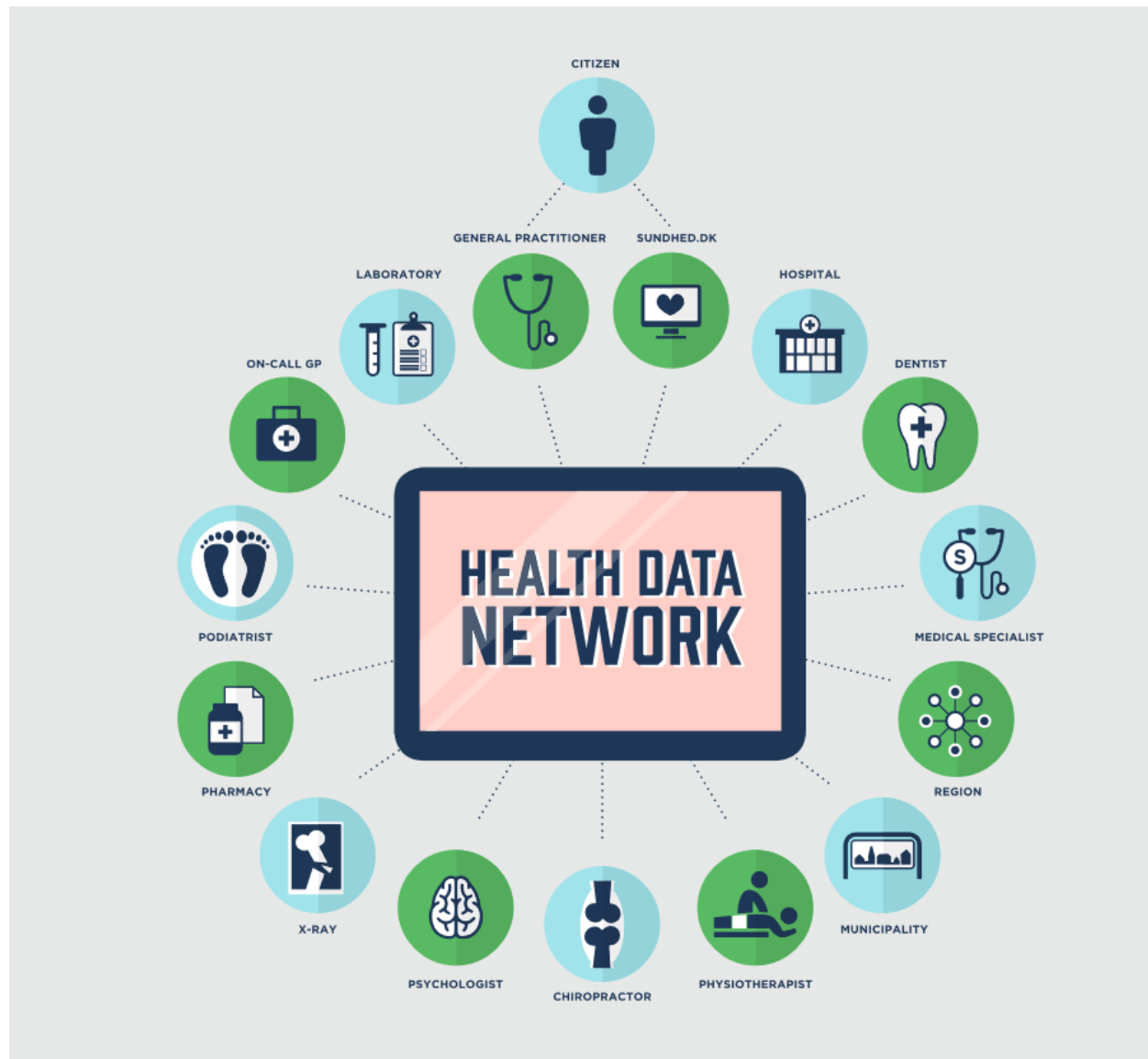
The content of MedCom communication builds on Danish profiling of **international standards and mutually recognised classification and code systems**. [e.g. NPU codes]

Work process in (most) medical laboratories in Denmark



- Most biochemical examinations are performed by 30 laboratories in major hospitals in Denmark (pop 6 mio).
- Laboratories handle 5-10 mio tests per year.
- Half of samples taken outside hospital by local physicians.
- Local physicians request tests electronically through **Webreq**.
- Laboratories have collection services in their region.
- The physician owns own software that is compatible with MedCom standards.
- A region may request physicians to use e.g. 6 of 30+ compatible softwares for receiving examination results.
- The physician is responsible for own IT administration and update of software.

What does this mean for a citizen



Final words



- The measurement process in most accredited labs are already today digital in recording, processing and transmission.
- There does exist protocols for data transmission - but they are sector specific.
- The ISO standards for accreditation of Laboratories, Reference Material Producers, PT Providers and Biobanks are supporting handling of electronic data.