

Big data in medicine

Central archiving of patient data to allow the discovery of new interrelationships: in Estonia and the United Kingdom, that is already becoming reality and other countries are likewise working to drive digital medicine forward. Big data analyses performed by supercomputers now make it possible to analyze all information together for more medical knowledge and improved guidance regarding therapy selections, thus ultimately benefiting the patient.

Day-to-day data



We are already today with our smartphones and wearables generating mountains of data every day. The same applies to modern medicine, where digital data are generated in the shape of X-rays, blood analyses and drug prescriptions, to name just a few.

World population

Medical data

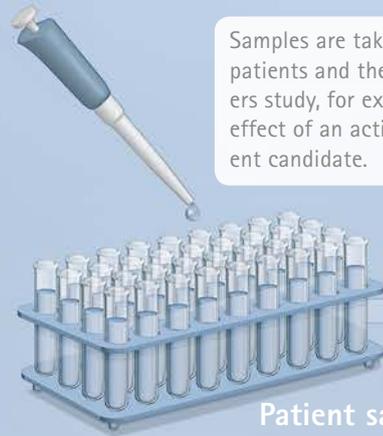


A defined group of patients is first selected for the question at hand. The patients are asked for their informed consent and have to agree to their data being used for research purposes.

Samples are taken from patients and the researchers study, for example, the effect of an active ingredient candidate.



Study group



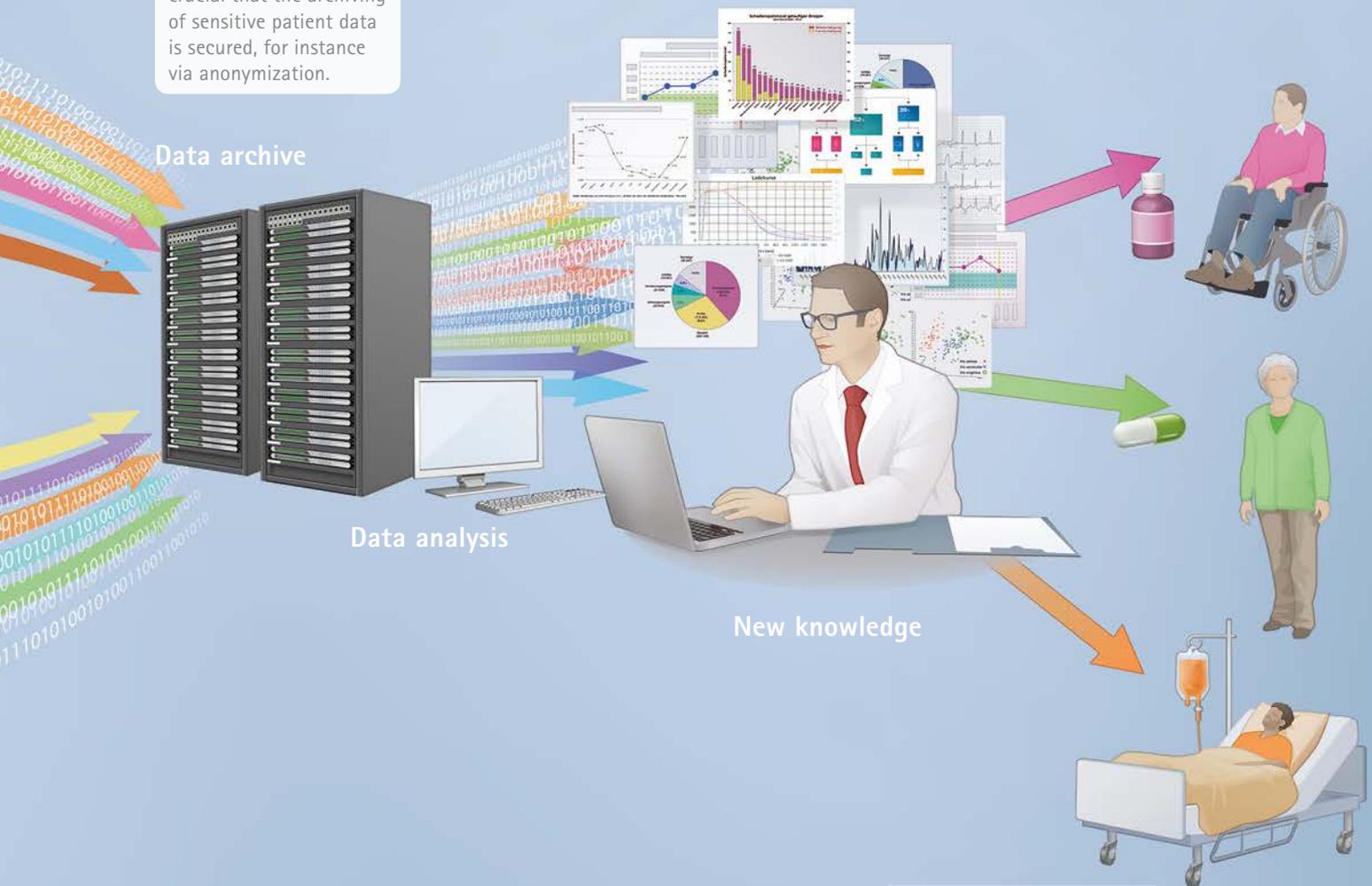
Patient samples



If it were possible to compile all relevant data on one central database, scientists would be able to leverage the full potential of these state-of-the-art technologies. The medical world could derive a lot of new knowledge. These data could likewise be used to optimize conventional clinical studies right from the beginning.

By taking into consideration all available information about the effects of the different drug products in real-life conditions (Real Life Evidence), the doctor can selectively prescribe the ideal treatment for each individual patient.

To ensure privacy, it is crucial that the archiving of sensitive patient data is secured, for instance via anonymization.



Data evaluation

Scientists employ IT support to analyze all the data generated.

The outcome is new findings about a disease, its progression and the respective therapeutic options. A new drug could be developed in a faster and more targeted way.



Sensors right next to the patient



Evaluating the data: Dr. Wilfried Dinh and Dr. Frank Kramer discuss the data recorded by a sensor patch. These high-tech plasters allow continuous measurement of, for example, the patient's cardiac function over about one week.

Most people glance at their smartphone when they first wake up, activating their digital identity before even getting out of bed in the morning. According to the Ericsson Mobility Report 2016, there are some 3.2 billion users worldwide. "Smartphones offer great new communication opportunities, in drug safety as elsewhere," says Dr. Matthias Gottwald, head of Research & Development Policy and Networking at Bayer's Pharmaceuticals Division.

Patients report a drug's side effects via an app

Together with an international team, he is working on an app that patients can use to report a medication's side effects. The European Union is supporting this collaboration between several pharmaceutical companies and academic institutes as part of the Innovative Medicines Initiative (IMI). The researchers are hoping to harvest reports on side effects from social networks as well. "Health care topics are discussed there as well. We're currently examining if this information can be used to improve drug safety," explains Gottwald.

However, connectivity doesn't end with the smartphones in our pockets. Devices known as wearables are gaining steadily in

popularity as well. Our daily technological companions range from wristbands that register our heart rate and physical activity to smartwatches. "These kinds of technologies are also of great interest for use in patient monitoring," says Dr. Frank Kramer, Biomarker Strategist in the Experimental Medicine Cardiovascular group at Bayer.

Patches monitor physical activity of patients

Researchers are using wearables, for example, in a study with heart failure patients. The patients are given a high-tech patch that allows continuous monitoring of vital medical parameters. "Patients wear the patch, which is equipped with several sensors, for a week. Although unobtrusive, the patch provides us with continuous information on the patient's heart rate, respiration, physical activity and much more," explains Kramer. The data are analyzed around the clock and any abnormalities are recognized immediately upon review. One enormous advantage of telemonitoring, as this procedure is known, is that the patient does not have to visit a doctor to have the data recorded. Also, data are collected continuously in patients' home surroundings (so-called



Constant companion: the high-tech plaster (right in photo) is supplied by the U.S. medical technology company Medtronic, a collaboration partner of Bayer.

"real life data") rather than at the doctor's office or study center using the snap-reading method. It allows Bayer scientists to collect information on the safety and efficacy of a new form of treatment in clinical studies earlier and more comprehensively. To this end, Bayer's experts are collaborating with Medtronic, a leading developer and manufacturer of medical sensor technology. Their main concern is how the data can be interpreted and optimally leveraged. "After all, we're generating a mountain of data. Already today, we can use many of these parameters to assess the health condition of a patient and evaluate the efficacy of the new active substance. But the potential offered by other data that we now have at our disposal thanks to new sensor technology is nowhere close to being exhausted," says Kramer. The researchers want to understand even better how these data can be used to optimize the treatment of each individual patient.



Dr. Matthias Gottwald,
head of Research & Development
Policy and Networking at Bayer

"We are currently investigating whether we can use information on drug side effects from social networks."

Making patient data available throughout Europe

Big data analysis offers enormous potential for the collection of new medical knowledge. However, any such process first has to overcome high data protection hurdles. Further complicating the issue are the different laws in the different European states. Bayer is coordinating a working group comprising representatives from 12 pharmaceutical companies and 10 public partners, which plans to standardize the legal framework for data protection regarding patient consent in clinical trials throughout Europe.



Jill Nina Theuring,
Legal Counsel at Bayer's
Pharmaceuticals Division

"The objective," says Jill Nina Theuring, Legal Counsel at Bayer's Pharmaceuticals Division and head of the working group, "is to reach a common understanding of the legal data protection requirements relating to the use of patient data and samples." The team will start its work in January 2017. It will review the existing regulations, conflict topics and previously proposed solutions. The working group is part of the "DO → IT" project, which aims to improve the underlying conditions for big data analyses in medicine. It is being funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

One parameter that is already well understood is the physical activity of a patient. "If we see that a patient taking a medication then has increased physical activity, we can deduce that he or she is feeling better and that the treatment is effective. What remains unclear is how big this increase has to be to be clinically meaningful and, for example, likely to improve the patient's prognosis and well-being in the long term," explains Kramer. It is these gaps in our knowledge among others that Bayer's researchers want to fill in collaboration with experts from the diagnostics and IT industries, by means of so-called register studies in which they can investigate the clinical significance of digital biomarkers, as these measurements are called.

Wearables that document our bodily functions are currently still a lifestyle product, but Kramer believes that these devices will eventually blossom into an integral health solution. "In the future, in particular for cardiovascular patients, I anticipate a multi-component system: drug treatment supported by sensors monitoring the therapeutic success and enabling individualized optimization."