



# BIOMARKER COMMERCIALIZATION

# #FactFriday

Browse through posts from our #FactFriday series all conveniently collected in one place and explore interesting facts about the biomarker field.

# What are Biomarkers and Why Are They Important?



Watch also How Biomarkers Can Improve the Drug Development Process:  
<https://www.youtube.com/watch?v=AZUhopmeUSk>

**Did you know, that the 9 out of 10 drug developments may fail, even though they went through the whole preclinical process like animal testing and other sorts of preclinical assays?**

Biomarkers can help to make clinical trials smarter and can lead to lower costs of drug development. They are critical to measure the effects of drugs under investigation on people during clinical trials.

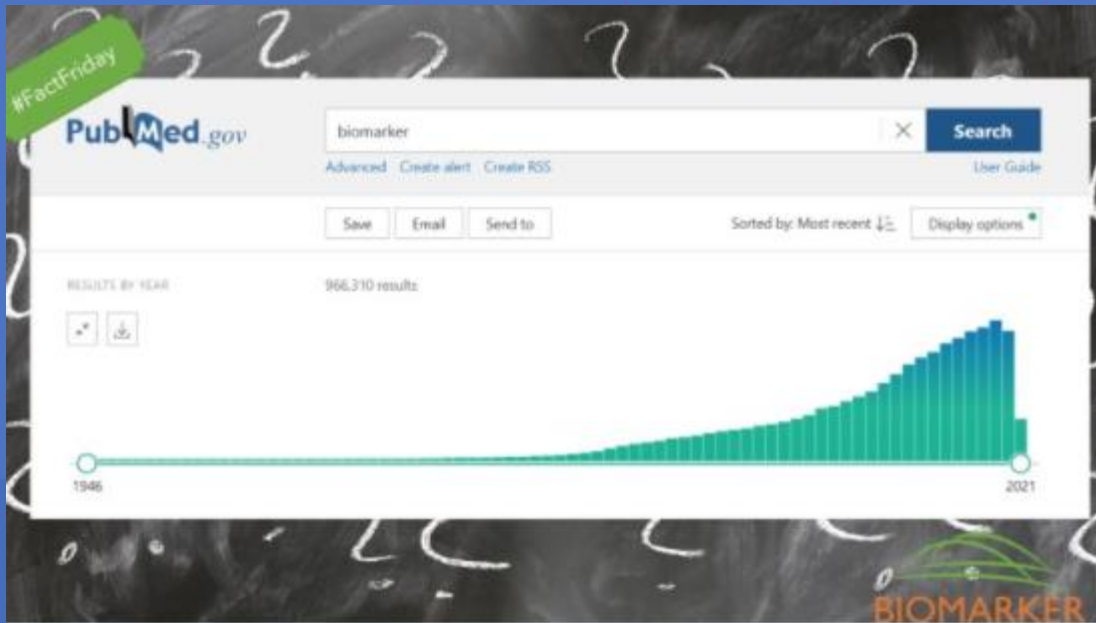
[Source: U.S. Food and Drug Administration (2017), What Are Biomarkers And Why Are They Important?, video available online: <https://youtu.be/Q1CwARpnfe8?t=27>]

1 000 000 000  
publications under the  
keyword "biomarker"

**Did you know, that you can now  
find almost one billion publications  
under the keyword "biomarker" on  
PubMed? (as of April 22, 2021)**

But only few biomarkers progress  
from discovery to become validated  
tools or diagnostics.

[Source: van Gool, A., Bietrix, F.,  
Caldenhoven, E. et al. Bridging the  
translational innovation gap through  
good biomarker practice. Nat Rev  
Drug Discov 16, 587-588 (2017)]



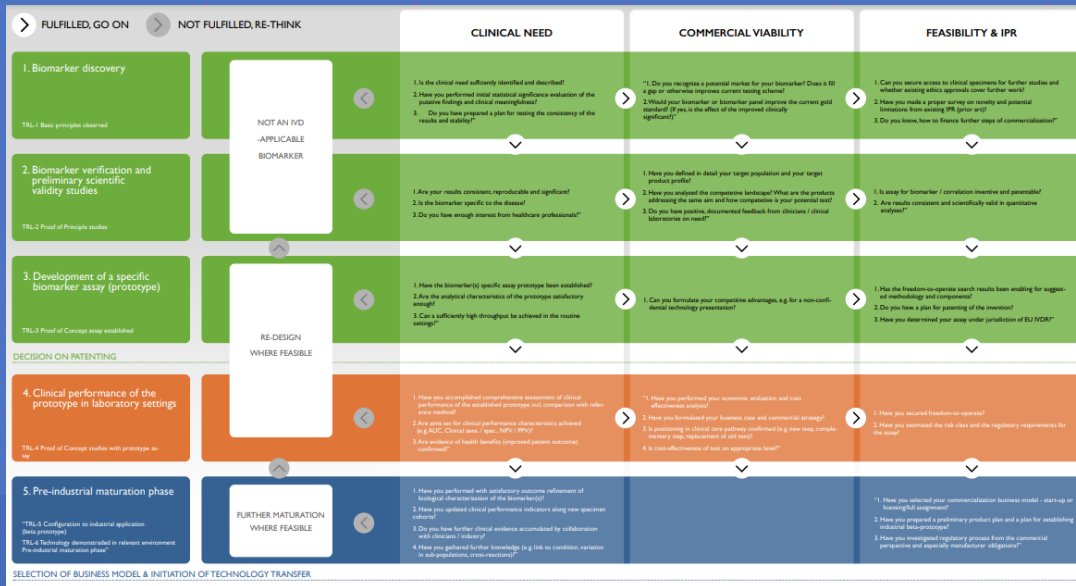
# TRL: Technology Readiness Levels – a product development scale

**Did you know that product developments can be classified by their maturity level according to TRLs?**

The Technology Readiness Level (TRL) scale is the most widely used tool for a maturity assessment and allows also a consistent comparison of maturity between different types of technologies.

The TRL concept was originally developed by the NASA - National Aeronautics and Space Administration to support the development of Space technologies and allow for more effective assessment of and better communication on the maturity of new technologies.

Find TRL definitions here: EU Commission (2014), Horizon 2020 - General Annex G, [https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014\\_2015/annexes/h2020-wp1415-annex-g-trl\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf)



BIC Flowchart: <https://biomarker.nu/review-tool>

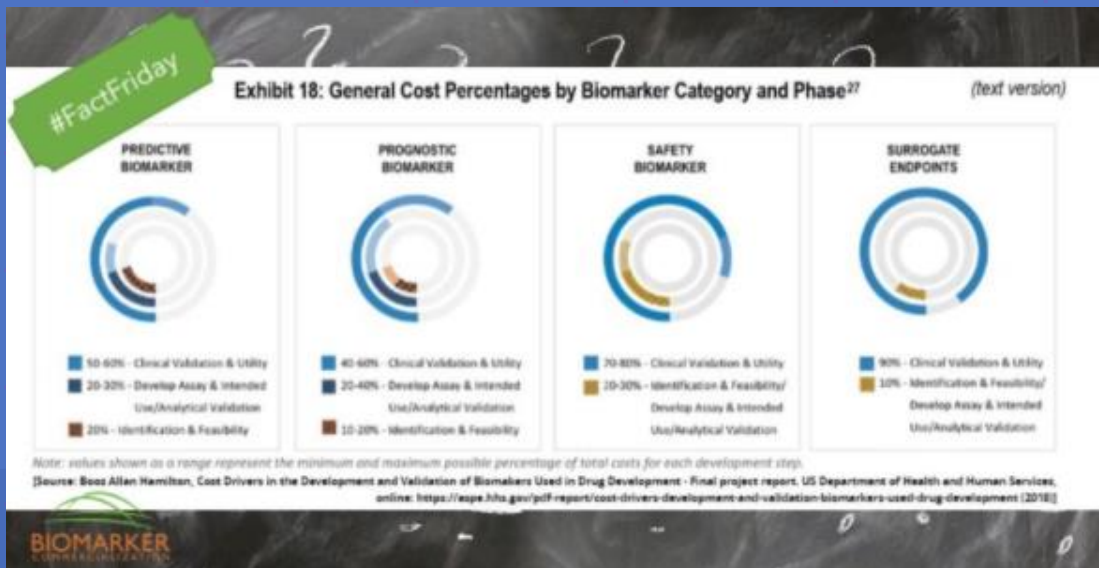


# Cost Drivers in the Development and Validation of Biomarkers

**Did you know, that clinical validation and utility is generally the most expensive phase in biomarker development?**

Depending on biomarker category the general development costs can vary between \$ 2 mio. for safety biomarkers and up to more than \$ 100 mio. for surrogate endpoints for common diseases. While the proportionate costs for the Identification and Feasibility phase average 20%, the costs for Clinical Validation and Utility phase range from 40% to 90%.

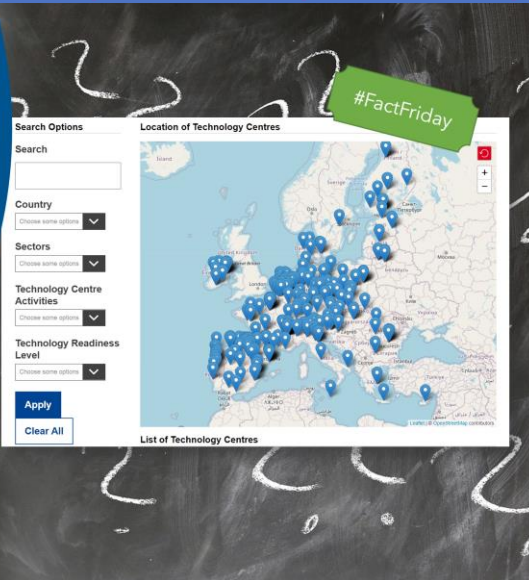
[Source: Booz Allan Hamilton, Cost Drivers in the Development and Validation of Biomarkers Used in Drug Development - Final project report. US Department of Health and Human Services, online: <https://aspe.hhs.gov/pdf-report/cost-drivers-development-and-validation-biomarkers-used-drug-development> (2018)]



# Support infrastructures

## ATI Technology Centres in Europe help SMEs cross the 'Valley of Death'

ATI (Advanced Technologies for Industry) Technology Centres are public or private organizations carrying out applied research and close-to-market innovation and help companies reduce the time-to-market for new innovation ideas.



**Did you know, that there are infrastructures in the European Union to help SMEs cross the 'Valley of Death' and go from lab to market?**

So-called ATI (Advanced Technologies for Industry) Technology Centres are public or private organizations carrying out applied research and close-to-market innovation (Technology Readiness Levels TRL 3 to 8, not necessarily the whole range) in Advanced Technologies for Industry.

Among these ATIs are e.g. Industrial Biotechnology, AI and Big Data - fields today strongly connected with biomarkers.

The European Commission provides an overview of the available ATI centers in the European Union:

<https://ati.ec.europa.eu/technology-centre/mapping>

Maybe it's worth having a look at it when you are searching for support to commercialize your biomarker-based invention.

(Are you a European center offering support for SMEs to bridge the gap from bench to bedside? Then it is possible to add your center there when you fulfill the relevant criteria!)

# EIC funding opportunities



Watch the video: <https://youtu.be/X5ZAJ3psZI>  
and learn more: [https://eic.ec.europa.eu/eic-funding-opportunities\\_en](https://eic.ec.europa.eu/eic-funding-opportunities_en)

**Did you know that there are a variety of instruments to support innovative ideas and start-ups in the European Union?**

One of these, for example, is the new EIC. The European Innovation Council has a budget of €10.1 billion to support game changing innovations throughout the lifecycle from early-stage research, to proof of concept, technology transfer, and the financing and scale up of start-ups and SMEs.

EIC offers several funding opportunities, e.g.

- 🔑 EIC Pathfinder: research support
- 🔑 EIC Transition: technology maturation/ business development
- 🔑 EIC Accelerator: funding and investments for Start-Ups and small companies
- 🔑 EIC Prizes: prizes and competitions for innovators

...

# Life science investors

## Different investors for different levels of maturity

Capital seekers who can already demonstrate initial success and have a demonstrably functioning and scalable business model are suitable for approaching venture capital (VC) companies.

Alternative? Private investors or business angles!



**Did you know, that depending on the maturity of a development, it can make sense to target different types of investors when seeking capital?**

Capital seekers who can already demonstrate initial success and have a demonstrably functioning and scalable business model are suitable for approaching venture capital (VC) companies. The investment level of venture capital companies starts usually at least 250 000 euros, depending on the company, but can also be several million euros.

The most active Life Science investors in the Baltic Sea Region are, e.g. Novo Holdings from Denmark, High-Tech Gründerfonds from Germany, YouNick Mint from Poland and Innovator Ventures from Finland.

[Source: FCF Fox Corporate Finance GmbH (2021), Novo holdings most active life sciences investor in Europe; online at: <https://t1p.de/coms> ]

Read more on different kinds of investors, like private investors and business angles in the BIC Biomarker Commercialization - now BIC BRIDGE Best Practice Handbook: <https://biomarker.nu/best-practices>



# What does reimbursement practice look like in Europe?



**Did you know, that although the market access process is harmonized for EU Member States, pricing and reimbursement decisions for medicines remain a national competence (subsidiarity principle) ?**

Various models of reimbursement or co-payment exist throughout Europe. Against this background, one should think about the use of the later product in the clinical pathway and the corresponding reimbursement regulations already at an early development stage of a biomarker-based product.

The 2018s WHO publication on Medicines Reimbursement Policies in Europe gives a comprehensive overview of the different systems in the European states (Link: [https://www.euro.who.int/data/assets/pdf\\_file/0011/376625/pharmaceutical-reimbursement-eng.pdf](https://www.euro.who.int/data/assets/pdf_file/0011/376625/pharmaceutical-reimbursement-eng.pdf))

# Zenodo- an open-access repository for research in Europe

**Did you know that there is a central, open-access repository for research in Europe called Zenodo?**

Zenodo is an open dissemination research data repository for the preservation and making available of research, educational and informational content. Access to Zenodo's content is open to all, for non-military purposes only. Zenodo is hosted by CERN and supported by the European Commission.

All research outputs from all fields of science are welcome. In the upload form you can choose between types of files: publications, posters, presentations, datasets, images, software, videos/audio and interactive materials such as lessons.

(But, be aware: Zenodo is not suitable for secret or confidential data.)

As an Interreg Baltic Sea Region project, BIC Biomarker Commercialization - now BIC BRIDGE created its own "community" on Zenodo, where you can find almost all BIC tools for supporting the development process for new biomarkers.

Check them:  
[https://zenodo.org/communities/bic\\_biomarkercommercialization\\_interregbsrproject/](https://zenodo.org/communities/bic_biomarkercommercialization_interregbsrproject/)

**Zenodo is a general-purpose open-access repository**

Zenodo welcomes multi-disciplinary research data from any individual, scientific community or research institution.

Have you already checked the BIC community ?!  
(<https://t1p.de/15oh>)



# Patents



**Did you know that patents are only valid in the country for which they are granted (so-called territoriality principle)?**

If you want to have your invention protected in other countries as well, there are various possibilities.

If you want to have an invention protected in only a few countries in addition to the national application, individual applications in the respective countries can be useful. An overview of the possibilities in the individual states of the EU can be found here: <https://innovaccess.eu/>.

If you are seeking broad regional or worldwide protection for your invention, you can apply for a European or international patent. This provides you with an efficient means of applying for patent protection for a large number of countries with just one application. However, a "world patent" does not exist.

## Class A, B, C, D...Examples

HPRA  
An Garda Síochána Tairg Síochána  
Health Products Regulatory Authority

\*Examples shown are for illustrative purposes. Final device classification depends on the intended purpose of the device & correct application of Regulation (EU) 2017/746

The diagram illustrates the classification of medical devices into four classes (A, B, C, D) based on their risk. A horizontal arrow points from left to right, with four colored circles representing the classes. Below each circle are icons of representative devices.

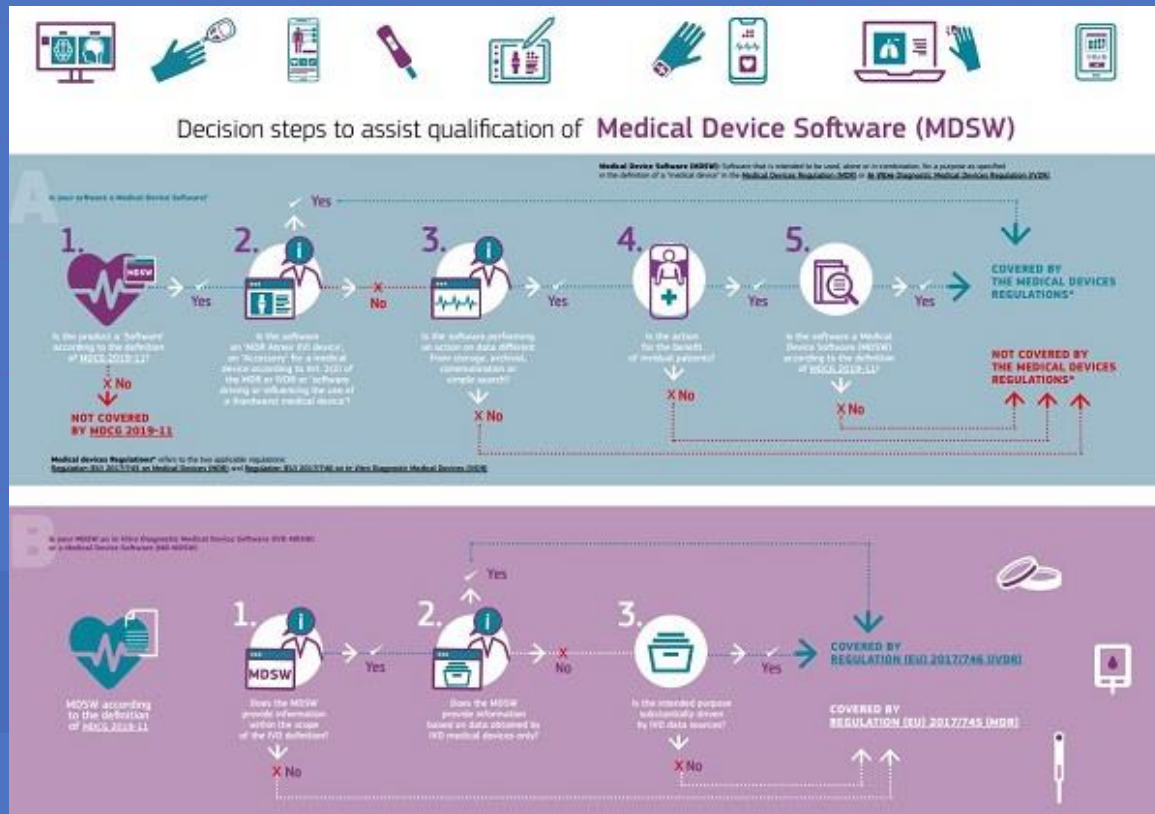
- Class A (Blue circle):** Includes icons of a syringe, a vial, a bottle, a piece of medical equipment, and two circular images of skin or tissue.
- Class B (Yellow circle):** Includes icons of a syringe, a person climbing a bar chart, a person climbing a ladder, and a person climbing a mountain.
- Class C (Orange circle):** Includes icons of a person with a heart, a DNA helix, a person with a heart, a person with a heart, and a person with a heart.
- Class D (Red circle):** Includes icons of a person with a heart, a person with a heart, a person with a heart, and a person with a heart.

These initial decisions for classification will influence many of the subsequent steps of commercialization to be followed. It is therefore essential to take these decisions carefully and to be precise.

Watch the webinar:  
[https://www.youtube.com/watch?v=1x1pVBe\\_oK8&t=130s](https://www.youtube.com/watch?v=1x1pVBe_oK8&t=130s)



# Decision steps to assist qualification of Medical Device Software

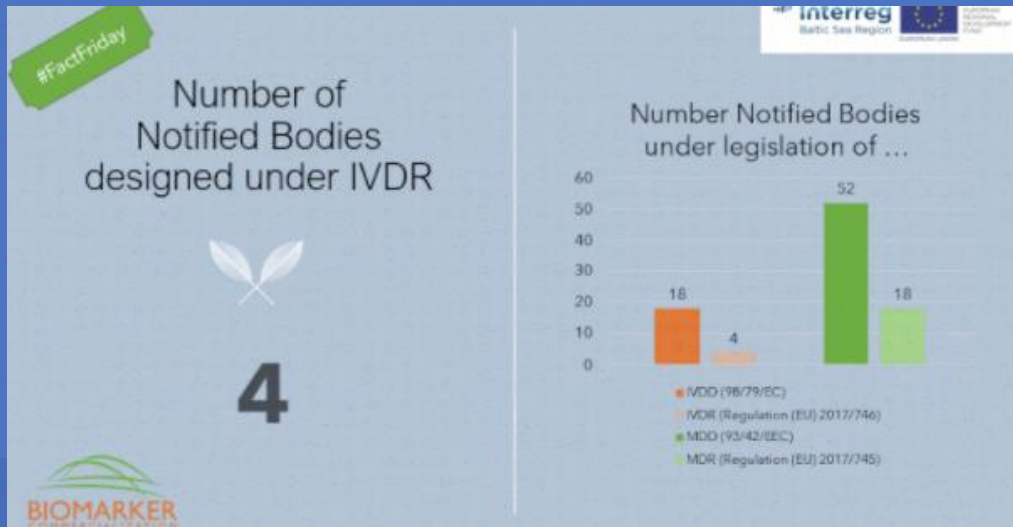


## Is your software a medical device?

The European Commission developed an infographic to help you determine whether your software is a medical device. It will also help you determine whether your medical device software is an In Vitro Diagnostic Medical Device Software (IVD MDSW) or a Medical Device Software (MD MDSW).

Access the document from this link:  
[https://ec.europa.eu/health/sites/default/files/md\\_sector/docs/md\\_mdcg\\_2021\\_mdsw\\_en.pdf](https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_mdsw_en.pdf)

# Number of Notified Bodies in EU: 4 (publication date: 12.2.2021)



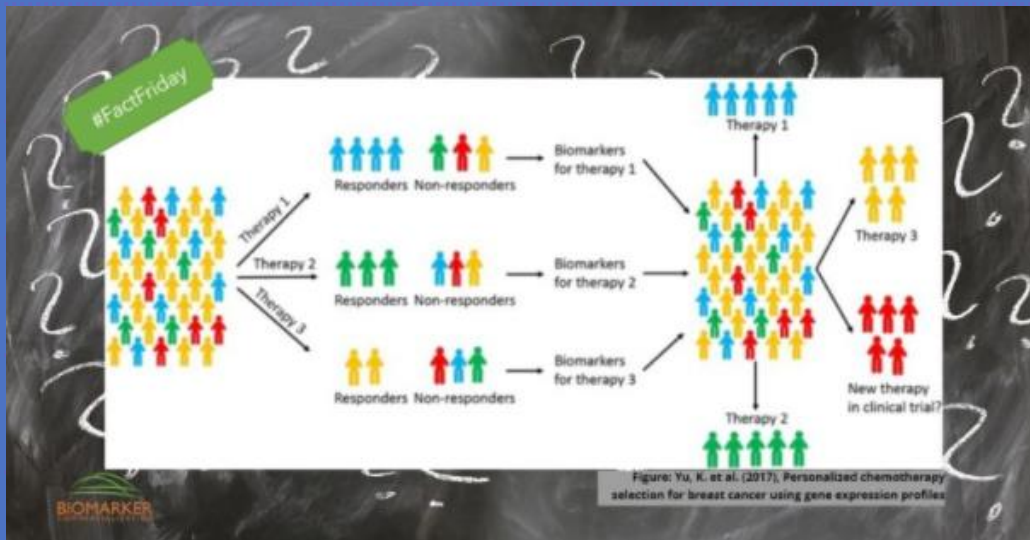
**Did you know, that so far only four Notified Bodies have been designated for the conformity assessment of in vitro diagnostics in Europe under the new in vitro diagnostics regulation (IVDR)?**

[Source: European Commission (2021), Nando Information System, online:  
[https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir\\_id=35](https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35) on 05.02.2021)

In this regard and taking into account stricter rules for the conformity assessment both for medical devices in general and In-vitro diagnostics in particular, it is more important than ever to be well prepared for the regulatory process.

And, to get in touch with a Notified Body as soon as possible.

# Diagnostic tests



**Did you know that, in Germany alone, 75 active substances have already been approved that require a mandatory diagnostic pre-test?**

Diagnostic and therapeutic agents form a tandem in the personalized medicine approach.

Diagnostic tests can basically provide three types of predictions:

- ✳ Whether the drug being considered is likely to be effective in that patient;
- ✳ Whether the specific patient is likely to tolerate the drug being considered;
- ✳ How the drug is best dosed for that patient.

The genetic, molecular, or cellular features that are examined by a diagnostic test before a prescribing decision are 🔑 biomarkers 🔒.

[Source: Verband Forschender Arzneimittelhersteller e.V., online: [vfa.de/personalisiert](https://vfa.de/personalisiert), (2021) ]

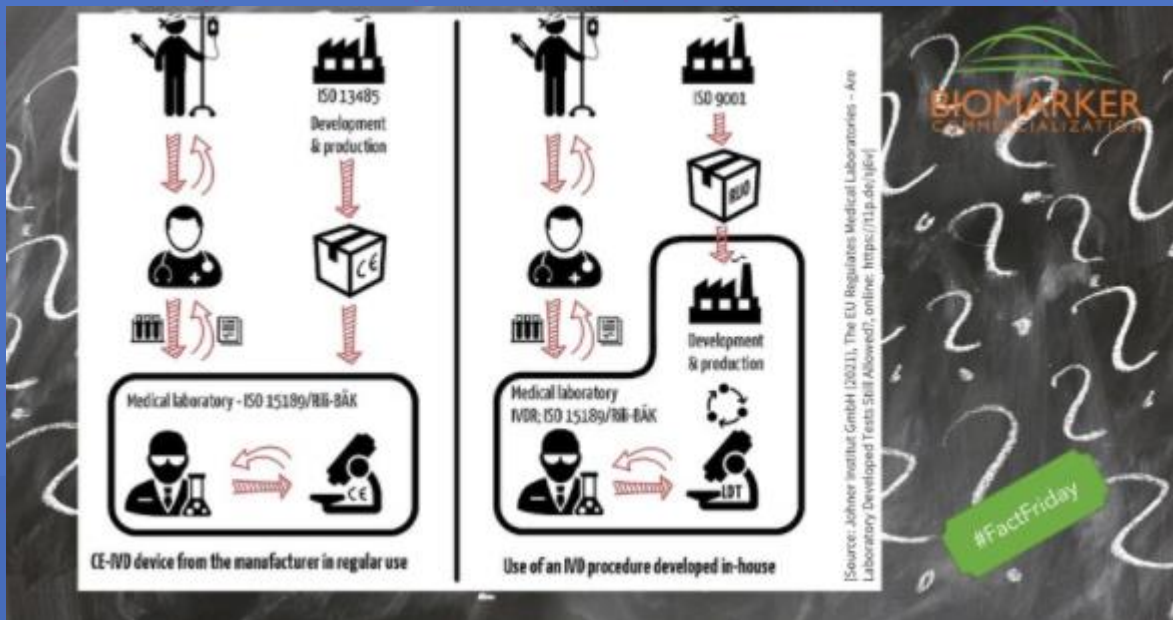
# Laboratory developed tests under EU IVD regulation – are they still allowed?

**Did you know that the new IVD regulation of the European Union explicitly regulates the use of laboratory developed tests for the first time?**

A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory.

The possibly most significant new requirement is, that LDTs for which there is an equivalent device on the market no longer have a right to exist. Health institutions will no longer be allowed to perform LDTs if an equivalent device is available on the market (after May 26, 2022).

[Source: Johner Institut GmbH (2021), The EU Regulates Medical Laboratories – Are Laboratory Developed Tests Still Allowed?, online: <https://www.johner-institute.com/articles/regulatory-affairs/and-more/the-eu-regulates-medical-laboratories-are-laboratory-developed-tests-still-allowed/>]





# Clinical Performance Characteristics

**Did you know that disease prevalence has a high impact on the accuracy of screening and diagnostic tests?**

The diagnostic accuracy is the overall probability that a patient will be correctly classified.

Let's have a look into an example:

The prevalence of a disease is about 20 cases/100 000 individuals, all of whom belong in the target population of the test. If you use an assay with 99 % diagnostic sensitivity and 99 % specificity, and test all the 100 000 individuals, you will probably catch all the 20 cases with the disease. However, if the diagnostic specificity of your assay is 99 %, you will get 1 % of false positive results, which is 1 000 cases. This means 50 false positives for each true positive case. If your diagnostic specificity is 95 %, you will get 5 % false positives, which is 5 000 cases, 250 for each true positive.



Learn more about Clinical Performance Characteristics in our BIC Guide - a tool addressing the whole Biomarker Commercialization Process - on <https://biomarker.nu/bic-guide>.

# Cancer biomarkers in the Era of Personalised Medicines

## BIOMARKERS



### CANCER GENETIC TESTING

Learn more about cancer biomarkers:  
[https://youtu.be/t\\_7wuuZAQAg](https://youtu.be/t_7wuuZAQAg)

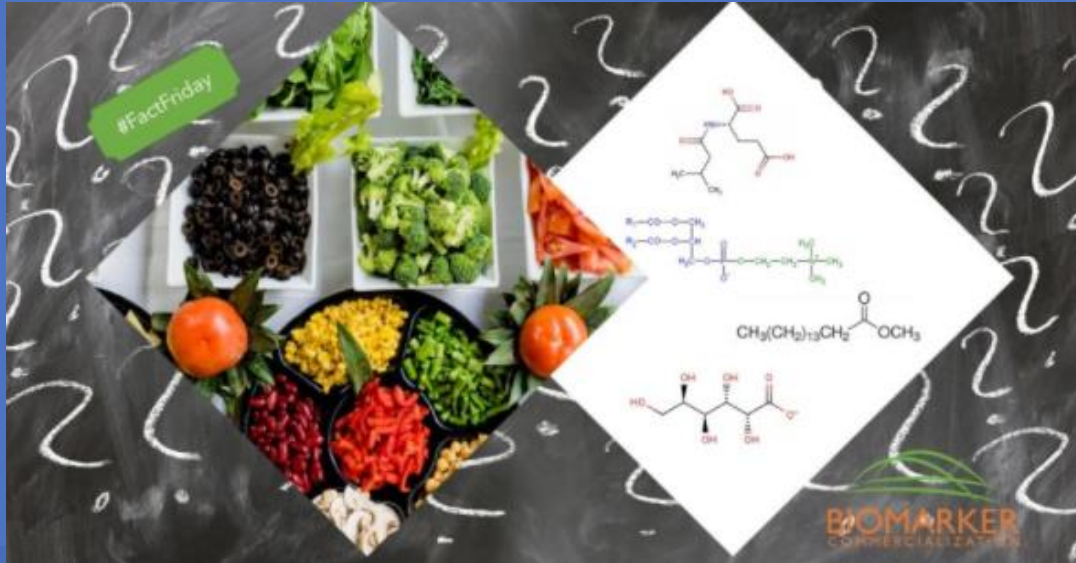
**Did you know, that the 9.6 million people die from cancer every year? By 2030, experts project cancer deaths to rise to 13 million!**

More than one third of cancer cases can be prevented. Another third can be cured if detected early and treated properly.

[Source: World Cancer Day, online:  
<https://www.worldcancerday.org/why-cancer>]

In this regard, biomarkers play an important role in cancer prevention, diagnosis and treatment.

# Biomarkers for food intake



**Did you know that there are biomarkers that characterize associations between the consumption of foods and health outcomes?**

So-called "Biomarkers of food intake" (BFIs) provide an accurate measure of intake, which is independent of the memory and sincerity of the subjects as well as of their knowledge about the consumed foods.

Thus, there is a whole range of biomarkers that allow conclusions to be drawn connection with the consumption of milk, eggs, yogurt and other foods. [Source: Münger et al. (2018), Biomarker of food intake for assessing the consumption of dairy and egg products, <https://genesandnutrition.biomedcentral.com/articles/10.1186/s12263-018-0615-5>]

# Rare diseases and biomarkers



**Did you know that there are more than 7000 so-called rare diseases?**

The definition of a rare disease in the European Union is a disease that affects fewer than 5 in 10.000 individuals within the general population. However, for a majority of these rare conditions, there are no specific therapies whose effectiveness have been evidenced in clinical trial studies.

Biomarkers have the potential to provide an invaluable tool for monitoring disease progression, prognosis, and response to drug treatment and to ultimately accelerate the discovery of therapeutics for rare diseases.

[Source: Bax, B.E. Biomarkers in Rare Diseases. Int. J. Mol. Sci. 2021, 22, 673.

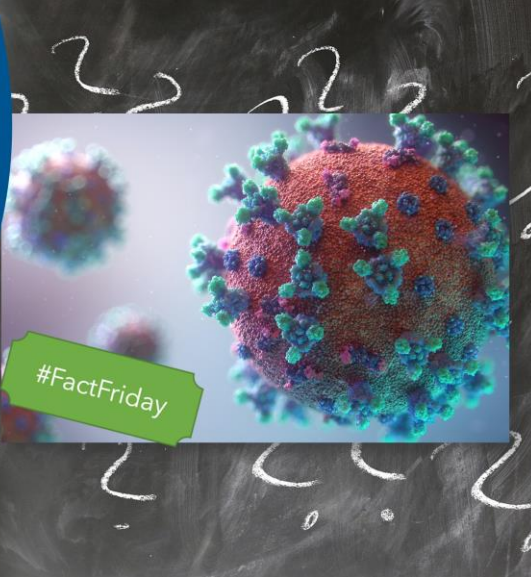
<https://doi.org/10.3390/ijms22020673> ]



# Biomarkers for determining the severity of COVID-19

## Biomarkers for determining the severity of COVID-19

Researchers at University of Zurich have identified distinct immunological signature biomarkers that can predict the severity of COVID-19 infection which could help in the treatment.



## Did you know, that immunological biomarkers can predict disease outcome, e.g. COVID-19?

Most SARS-CoV-2 infected people develop no or only mild symptoms. However, some patients require intensive medical care and suffer long-term health consequences. A biomarker could help to identify and treat these patients.

The number of natural killer T cells in the blood seems to be such an useful biomarker to predict the severity of COVID-19 infection and could now help in the treatment. [Source: Kreutmair, S. et. al (2021), Distinct immunological signatures discriminate severe COVID-19 from non-SARS-CoV-2-driven critical pneumonia, Immunity - doi: 10.1016/j.immuni.2021.05.002, online available at <https://t1p.de/cbo3>]

This rapid research success is the exception rather than the rule in the field of biomarkers, but highlights the importance of biomarkers for the detection and treatment of serious medical events!

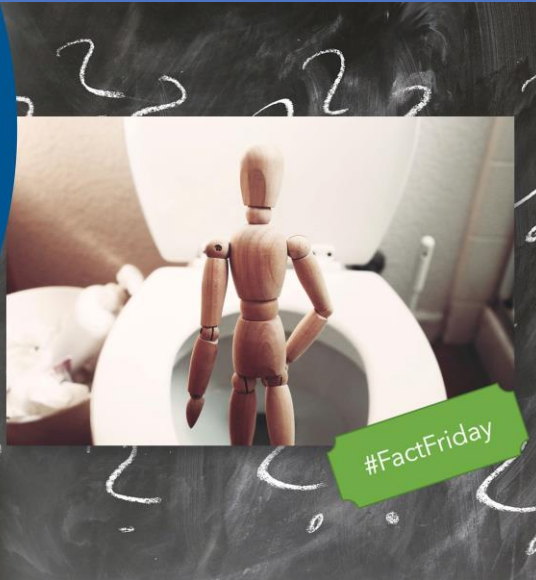
To support the development of biomarker-based technologies, the BIC project provides a set of tools to make more biomarker projects even more successful in the future!

# Non-invasive biomarkers

## Non-invasive biomarkers for cancer diagnostics

Finding non-invasive diagnostic biomarkers found in urine and saliva would allow for frequent monitoring and long-term surveillance for a particular disease types.

And non-invasivity can represent a great competitive advantage!



## Did you know, that non-invasive biomarkers can help diagnose specific cancers?

Finding non-invasive diagnostic biomarkers found in urine and saliva would allow for frequent monitoring and long-term surveillance for a particular disease types. This has led to novel biomarkers found in urine for endometrial cancer.

[Source: Njoku, K. et. al (2022), Urinary Biomarkers and Their Potential for the Non-Invasive Detection of Endometrial Cancer, Front Oncol. - doi: 10.3389/fonc.2020.559016, online available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7670058/>]

Especially when investigating a biomarker that is suitable to detect a disease for which another diagnostic test already exists, it can be a great competitive advantage if a new biomarker can be measured non-invasively.

The importance of biomarker tests already available on the market for one's own discovery can also be read in the Best Practice Handbook. One of the tools from the BIC Biomarker Commercialization - now BIC BRIDGE project to support biomarker translation. Check the Best Practice Handbook: <https://biomarker.nu/best-practices>

# Predictive biomarkers – the key to precision treatment

## Did you know that predictive biomarkers measure if a drug is working?

A predictive biomarker is usually measured before treatment and provides information on the probability of response to a particular therapy. Measurement of validated biomarkers is the key requirement in introducing precision treatment for e.g., breast cancer.

One example of a predictive biomarker is HER2. Measuring HER2 biomarker can show if Trastuzumab, a drug for breast cancer, is working.

[Source: Michael J. Duffy, Norma O'Donovan, Enda McDermott, John Crown. Validated biomarkers: The key to precision treatment in patients with breast cancer. The Breast, Volume 29, 192-201, (2016), <https://www.sciencedirect.com/science/article/pii/S0960977616301187>]

To support the development of biomarker-based technologies, the BIC project provides a set of tools to make more biomarker projects even more successful in the future!

### Predictive Biomarkers

A predictive biomarker is usually measured before treatment and provides information on the probability of response to a particular therapy.

BIC BRIDGE is developing free tools to advance the use of new biomarkers in precision treatment.



#FactFriday

Photo from National Cancer Institute @nci



# Lipid Biomarkers



**Did you know that there are several types of lipid biomarkers which can help identify people at risk for neurodegenerative diseases such as Alzheimer's disease?**

Lipids play fundamental roles in the pathogenesis of AD and some of them have a prognostic and diagnosis value. This may pave the way for the identification of new therapeutic targets, new effective drugs and / or new treatments.

Understanding of lipid biomarkers and apolipoprotein E-mutations can identify people at risk and diet interventions can help mitigate the onset of the disease. Lowering serum cholesterol and statins can reduce the risk of developing Alzheimer's.

[Source: Zarrouk A et al. Lipid Biomarkers in Alzheimer's Disease. Curr Alzheimer Res. 2018 Feb 22;15(4):303-312. <https://pubmed.ncbi.nlm.nih.gov/28474568/>]

To support the development of biomarker-based technologies, the BIC project provides a set of tools to make more biomarker projects even more successful in the future!



# Diabetes biomarker hemoglobin A1c

## Hemoglobin A1c

Hemoglobin A1c (HbA1c) may be considered as a biomarker for the presence and severity of hyperglycemia, implying diabetes or prediabetes

BIC BRIDGE is developing free tools to translate new biomarkers to the clinic



#FactFriday



## Did you know that there are several types of biomarkers used to diagnose and manage diabetes?

Biomarkers may reflect the presence and severity of hyperglycemia (ie, diabetes itself) or the presence and severity of the vascular complications of diabetes.

Hemoglobin A1c (HbA1c) may be considered as a biomarker for the presence and severity of hyperglycemia, implying diabetes or prediabetes, or, over time, as a "biomarker for a risk factor".

In the future, we can be optimistic that new blood and tissue-based biomarkers will enable the detection, prevention, and treatment of diabetes and its complications long before overt disease develops.

[Source: Lyons TJ, Basu A. Biomarkers in diabetes: hemoglobin A1c, vascular and tissue markers. Transl Res. 2012 Apr;159(4):303-12.

<https://pubmed.ncbi.nlm.nih.gov/22424433/>]

# Digital Biomarkers

## Digital Biomarkers

Wearables allow collection of digital biomarkers like sleep, blood oxygen levels, pulse, and step count, which are being correlated to help healthcare professionals give actionable insight on a person's biology.



#FactFriday

Photo by Onur Binay on Unsplash

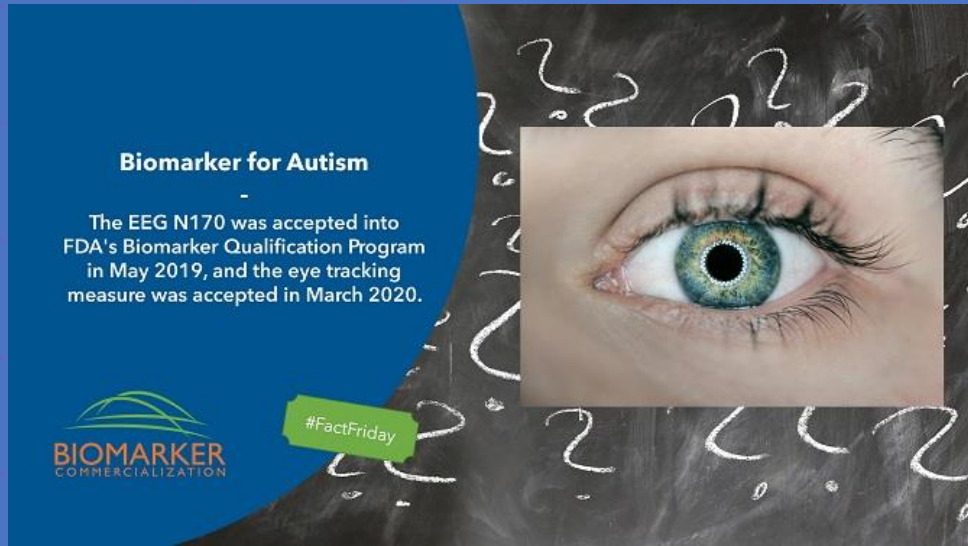


**Did you know, new wearable technologies create data to develop novel digital biomarkers?**

Wearables allow collection of digital biomarkers like sleep, blood oxygen levels, pulse, and step count, which are being correlated to help healthcare professionals give actionable insight on a person's biology.

[Source: Babrak, Lmar M., et al. "Traditional and digital biomarkers: two worlds apart?". *Digital biomarkers* 3.2 (2019): 92-102.  
<https://pubmed.ncbi.nlm.nih.gov/32095769/>]

# Biomarker for Autism



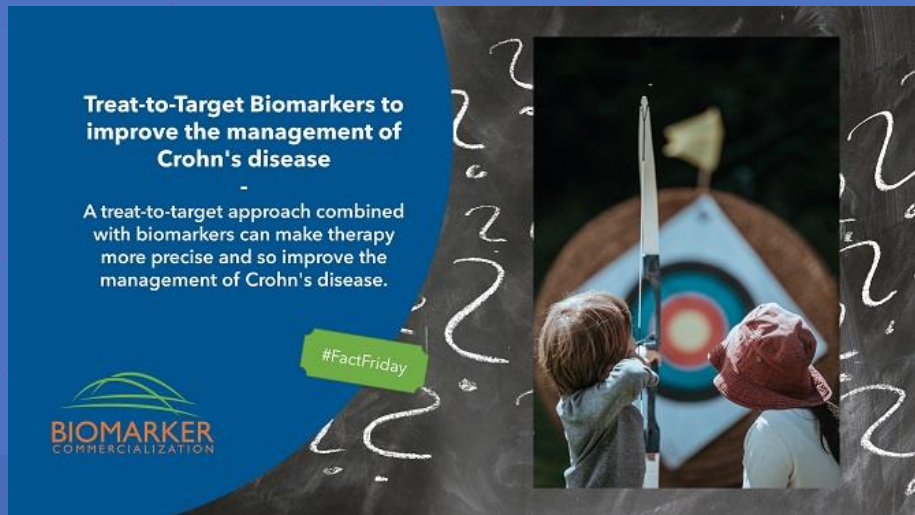
**Did you know that there is a biomarker for determining autism?**

The EEG N170 was accepted into FDA's Biomarker Qualification Program in May 2019, and the eye tracking measure was accepted in March 2020.

The EEG N170 measure is the first psychiatric biomarker accepted in the FDA Biomarker Qualification Program.

Read more about the FDA acceptance of the EEG N170 LOI: <https://fnih.org/our-programs/biomarkers-consortium/autism-biomarkers>

# Treat-to-Target Biomarkers to improve the management of Crohn's disease



## Did you know that precision therapy using specific biomarkers is being used for Crohn's disease?

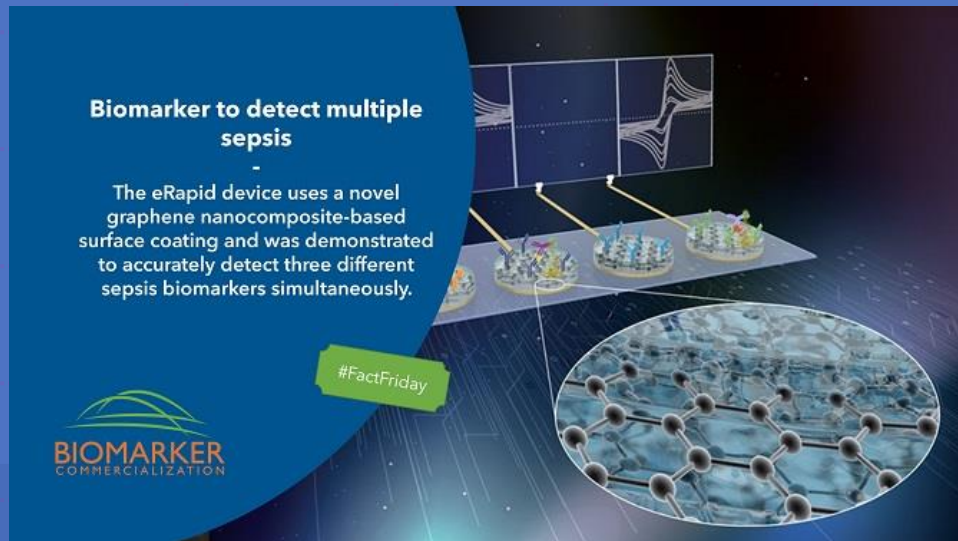
A treat-to-target approach [whereby treatment decisions are based on close monitoring of inflammatory biomarkers] can make therapy more precise and so improve the management of Crohn's disease.

[Source: Colombel JF et al. Outcomes and Strategies to Support a Treat-to-target Approach in Inflammatory Bowel Disease: A Systematic Review. J Crohns Colitis. 2020 Feb 10;14(2):254-266. <https://pubmed.ncbi.nlm.nih.gov/31403666/>]

More on this topic:  
<https://www.gastroenterologylearningnetwork.com/exclusive/gastroenterology/inflammatory-bowel-disease/whats-new-management-crohn-disease>



# Biomarker to detect multiple sepsis



**Did you know, eRapid electrochemical sensor technology now enables sensitive, specific, and multiplexed detection of clinically relevant sepsis biomarkers in whole blood.**

The device uses a novel graphene nanocomposite-based surface coating and was demonstrated to accurately detect three different sepsis biomarkers simultaneously.

It has the potential to revolutionize point-of-care diagnostics not only to test for sepsis biomarkers, but a much broader range of biomarkers that can be multiplexed in sets to report on the states of many diseases and conditions.

[Source: [wyss.harvard.edu](http://wyss.harvard.edu)]

# An all-in-one health biomarkers monitor

**Did you know, this soft and stretchy patch can monitor the wearer's blood pressure and biochemical levels at the same time.**

It would serve as a great tool for remote patient monitoring, especially during the COVID-19 pandemic when people are minimizing in-person visits to the clinic.



[Source: [ucsdnews.ucsd.edu](https://ucsdnews.ucsd.edu)]

# Microneedle bandage detects malaria rapidly

**Did you know, a microneedle bandage that can rapidly detect the presence of malaria?**

The patch draws upon protein biomarkers contained in dermal interstitial fluid. This fluid contains a multitude of biomarkers for various diseases, such as malaria, which can be used for rapid testing.

## Microneedle bandage for rapid detection of malaria

The patch draws upon protein biomarkers contained in dermal interstitial fluid.

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[Source: [news.rice.edu](https://news.rice.edu)]

# Detecting cancer biomarkers in urine

**Did you know, a new method can identify cancer-causing substances in the urine, which could lead to earlier cancer diagnosis?**

Extracellular vesicles (EVs) are cell-derived nanovesicles found in most types of body fluids that play a critical role in intercellular communication and transport biological signals for regulating diverse cellular functions.

In tests, the direct detection of urinary EVs from patients with bladder cancer was successful.

[Source: [medicaldesignandoutsourcing.com](https://www.medicaldesignandoutsourcing.com)]

## Detecting cancer biomarkers in urine

A new method can identify cancer-causing substances in the urine, which could lead to earlier cancer diagnosis.

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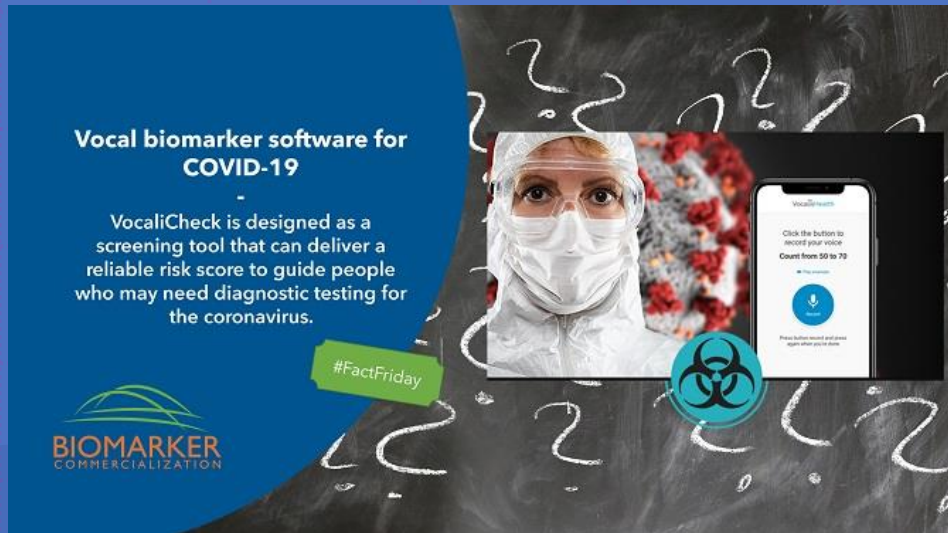


# Vocal biomarker software for COVID-19

## Did you know, an artificial intelligence can screen for COVID-19?

VocaliCheck is designed as a screening tool that can deliver a reliable risk score to guide people who may need diagnostic testing for the coronavirus.

A smartphone using the software records users counting from 50 to 70 and transforms their voice recording to a picture (spectrogram) containing 512 features. The software uses AI to compare each spectrogram to a composite picture based upon the voice recordings of COVID-19-positive clinical trial participants.



[Source: [vocalishealth.com/](https://vocalishealth.com/)]

# Nanosensors for Disease Biomarkers

**Did you know, a nanosensor can detect disease biomarkers in exhaled breath?**

Nanosensors rapidly analyze the components of exhaled breath to detect trace molecules associated with certain diseases.

Their performance and accuracy improved by designing protein-encapsulated nanocatalysts.



[Source: [phys.org](https://phys.org)]

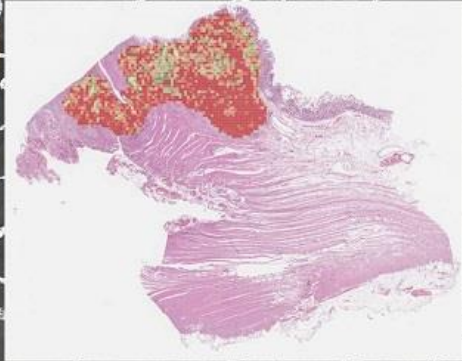
# AI-based marker to improve the treatment of colon cancer

## AI-based marker to improve the treatment of colon cancer

The marker uses deep learning and digital scanning of conventional hematoxylin and eosin-stained tumor tissue sections.

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## Did you know, AI-based marker can improve the treatment of colon cancer?

A clinically useful prognostic marker uses deep learning and digital scanning of conventional hematoxylin and eosin-stained tumor tissue sections.

The assay has been extensively evaluated in large, independent patient populations, correlates with and outperforms established molecular and morphological prognostic markers, and gives consistent results across tumor and nodal stages.

[Source: [medicalxpress.com/news/](https://medicalxpress.com/news/)]

# Wearable device measures cortisol in sweat

**Did you know, a stretchy patch that, applied directly to the skin, wicks up sweat and measures how much cortisol a person is producing?**

By drawing in a bit of sweat, a patch developed in the lab of Alberto Salleo can reveal how much cortisol a person is producing.

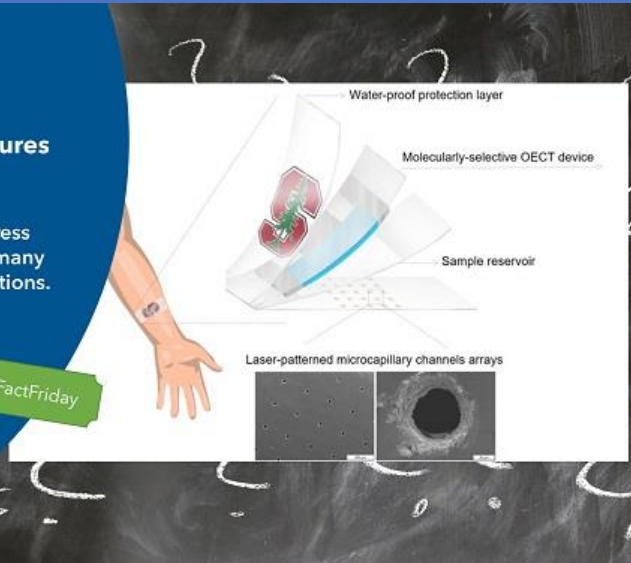
Cortisol is known as the stress hormone but is involved in many important physiological functions.

[Source: [news.stanford.edu](https://news.stanford.edu)]

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# Microbial Biomarkers

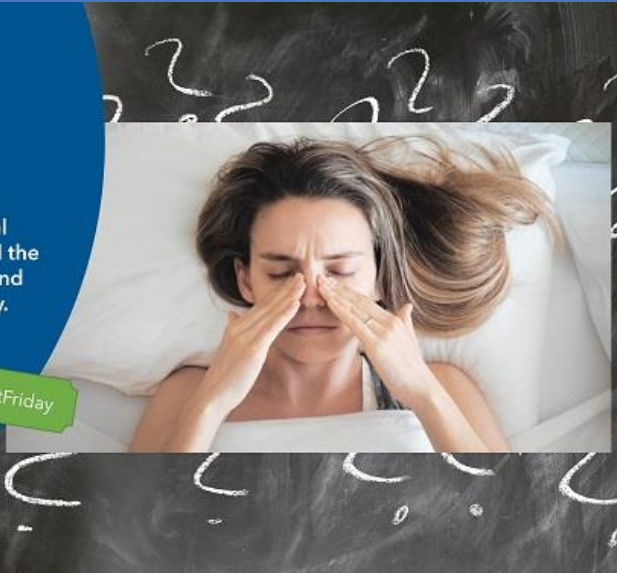
**Did you know that the nasal microbiome of people suffering from allergic rhinitis is commonly altered?**

Identifying these alterations can help understand the mechanism of such chronic disease and apply more successful therapy.

## Microbial biomarkers

Identifying alterations of nasal microbiome can help understand the mechanism of allergic rhinitis and apply more successful therapy.

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[Source: Bender ME et al. A Comparison of the Bacterial Nasal Microbiome in Allergic Rhinitis Patients Before and After Immunotherapy.

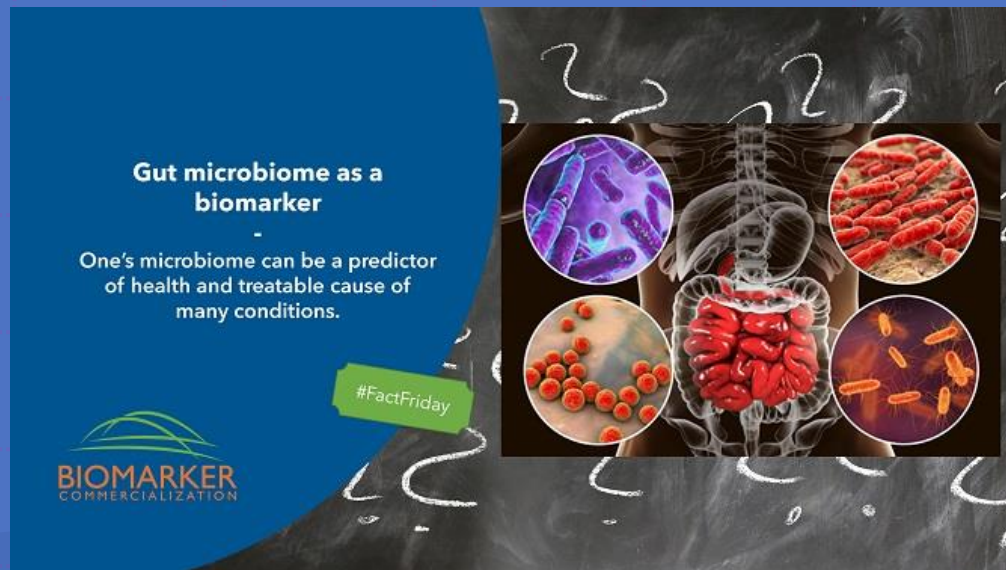
Laryngoscope. 2020 Dec;130(12):E882-E888.  
<https://pubmed.ncbi.nlm.nih.gov/32181890/>]

# Gut microbiome as a biomarker

**Did you know that gut microbiome diversity correlates not only with intestinal conditions such as irritable bowel syndrome (IBS) but with a range of central nervous system conditions ranging from depression to autism spectrum disorder (ASD)?**

One's microbiome can be a predictor of health and treatable cause of many conditions.

Furthermore, probiotic treatment and dietary changes tailored to healthy microbiome regeneration have proven to bring benefits in ameliorating multiple conditions.



[Source: IBS: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6769995/>

ASD: <https://www.frontiersin.org/articles/10.3389/fpsy.2020.550593/full>

Depression: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5319175/>

# High throughput and miniaturization of biomarker diagnostics

## High throughput and miniaturization of biomarker diagnostics

Development of digitalized diagnostics allows faster and more precise assessment through elimination of human labor and error.



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Year by year more evidence about the devastating health effects of antibiotic usage appears. New, deadly, antibiotic resistant bacteria are born due to antibiotic overuse. Yearly over 2.8 million people suffer from antibiotic resistant infections and over 35000 people die.

Development of digitalized diagnostics allows faster and more precise assessment, through elimination of human labour and error. This helps avoid vain use of antibiotics, and/or choice of the right treatment depending on the detected pathogen.

Antibiotic resistant strains:

<https://www.cdc.gov/drugresistance/index.html>

# High throughput and miniaturization of biomarker diagnostics

**Did you know, a classic COVID-19 PCR test can take over 45 minutes depending on human handling speed?**

Recently the world has shown us the need for faster and more precise diagnosis based on biomarkers such as DNA or RNA.

Technologies allowing the same process in under 15 minutes can greatly reduce standby periods during which people remain active spreaders and are not submitted for proper treatment.

## High throughput and miniaturization of biomarker diagnostics

Development of digitalized diagnostics allows faster and more precise assessment through elimination of human labor and error.

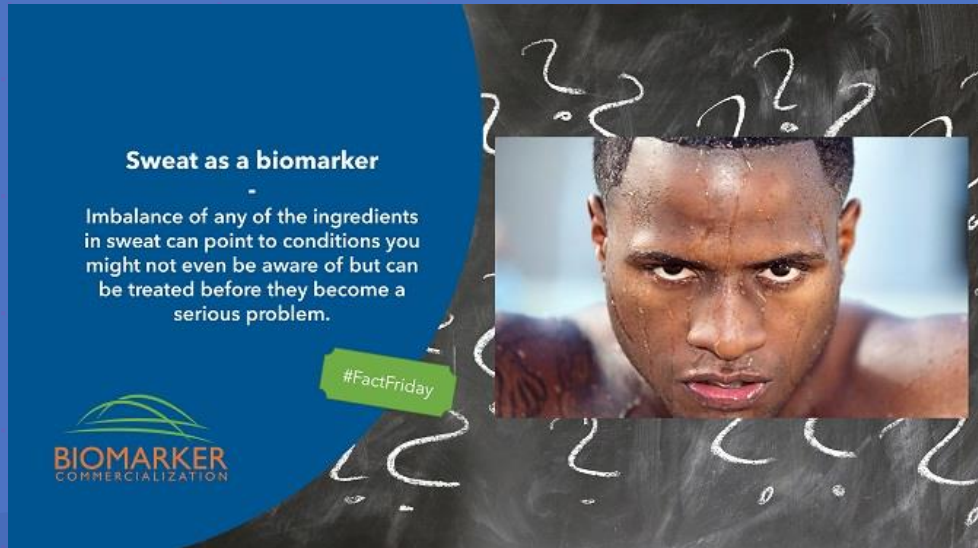
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# Sweat as a Biomarker



**Did you know, you can detect the activity of your immune system through sweat analysis?**

Except for minerals, sweat contains a range of proteins, lipids, and other substances. Imbalance of any of the ingredients can point to particular conditions you might not even be aware of, but can be treated before they become a serious problem.

Sweat prognostics:

<https://www.karger.com/Article/Fulltext/504387>