The future of **Diagnostics** follows a new plan: 
Tailored biomarkers for health.
Biomarkers are rapidly becoming the main drivers of innovation for medicine in the 21st century. Because they improve the potential to tailor treatment to the specific needs of individual patients, they are a critical prerequisite to personalized medicine.

Biocrates identifies and quantifies endogenous metabolites in body fluid or tissue samples and develops them into powerful biomarkers. By focusing on metabolites, we look at the functional endpoints of diseases and drug action – a technology called metabolomics.

Biocrates – bringing society one step closer to the goal of personalized medicine.

Klaus Weinberger, PhD, CSO

Elgar Schnegg, MBA, CEO
Metabolomics in Personalized Health

Measurable changes in the concentration of metabolites in biofluids or tissues can be used to detect changes in health or disease states. This approach lies at the foundation of metabolomics, which uses a combination of high-resolution mass spectrometry and multivariate statistical methods providing information on hundreds of metabolites – all at the same time.

Metabolomics in Drug Discovery

Supporting pharmaceutical companies in developing companion diagnostics is another main component of the Biocrates business and scientific portfolio. Companion diagnostics – tests assisting in making treatment decisions – are becoming an integral part of the development of targeted therapies. They help determine how a drug works in the body, find its most effective dose, assess whether it is safe and effective, and identify patients most likely to respond or least likely to suffer an adverse reaction.
By comparing ‘healthy’ and ‘diseased’ samples, biomarker panels can be identified that will later not only help differentiate between health and disease but will be able to spot any deviation from normal well before the disease becomes manifest.

The strategy of Biocrates is focused on the discovery and validation of new biomarkers for early disease detection, which will ultimately result in a new range of diagnostics, e.g., for diabetes mellitus, kidney disease, sepsis, stroke, and cancer. Biocrates has screened and identified meaningful biomarker candidates for these diseases and has also successfully developed the world’s first metabolomics-based kit product.

Case Study I:
Biomarker Discovery in Diabetic Nephropathy

A fully blinded clinical study on well-characterized patients with different stages of diabetic and non-diabetic nephropathy (n = 79, Montpellier University Hospital) was completed as part of an EU-funded consortium.

The study yielded high significance for all cohort comparisons (Figure 1), confirmed some biomarkers that had already been found in previous studies (e.g., nephrotoxicity of model compounds, early prognostic markers for acute rejection and chronic nephropathy in kidney transplant patients), and identified additional ones that had not been published earlier.

Based on these results, two medical claims were designed (highly sensitive detection of impaired kidney function without focus on underlying etiology and individual assessment of disease progression at initial diagnosis of chronic kidney disease).

Case Study II:
Companion Diagnostic Project for Diabetes

A mouse model of type II diabetes was used to compare the antidiabetic efficacy of a new drug candidate with the current standard of treatment. Although the mouse model used in this study was first described more than 40 years ago, Biocrates succeeded in analyzing the metabolic profile in mice in unprecedented detail. By applying surrogate biomarkers for various aspects of pathophysiology, such as insulin resistance, oxidative stress, and inflammation, the study showed that the drug candidate was in many ways equally effective as, or even more effective than, the currently licensed standard drug (Figure 2), without showing any of its off-target effects.
Fig. 1
High-specificity diagnosis of diabetic nephropathy
Clinical cohorts with different disease severities (D3 – D5) were able to be clearly differentiated based on their metabolic profile.

Fig. 2
Effect of the drug candidate on one metabolomic biomarker in mice
Based on the results of this preclinical study, the pharmaceutical company testing the new drug candidate decided to further pursue the development of its new compound. A slightly modified member of this class of compounds is now in clinical development and is showing highly promising efficacy in humans.
Founded in 2002, BIOCRATES Life Sciences AG is dedicated to further developing and harnessing a relatively young technology referred to as metabolomics. Incorporating an innovative, integrated mass spectrometry technology platform, our quantitative approach enables immediate identification of more than 800 metabolites, measurement of their absolute concentrations, and mapping to their respective pathways. Many of these metabolites could ultimately be developed into meaningful biomarkers.

Biocrates has already analyzed a broad range of samples from diverse species, and new analytical methods for novel applications are constantly being added.

Metabolite Classes
analyzed so far:
- Amino acids: proteinogenic and non-proteinogenic
- Acylcarnitines and free carnitine
- Bile acids
- Biogenic amines and polyamines
- Eicosanoids and other oxidized polyunsaturated fatty acids (PUFAs)
- Free and total fatty acids
- Glycerophospholipids
- Intermediates of central energy metabolism
- Monosaccharides
- Oxysterols
- Phospholipids and ceramides (lipid assay)
- Sphingomyelins
- Vitamins: water-soluble vitamins/vitaminoids and fat-soluble vitamins

Additional classes under development

Species
analyzed so far:
Human, primate, rat, mouse, dog, guinea pig, bovine, sheep, pig

Samples
analyzed so far:
- Fluid: plasma, serum, urine, blood spots, whole blood, bronchoalveolar lavage, cerebrospinal fluid
- Tissue: liver, kidney, brain, lung, prostate, ovary, breast
- Cell: erythrocytes, myocytes, peripheral blood mononuclear cells, dendritic cells, fibroblasts, hepatoma cell lines