

# numares at a glance

*company overview 2014*



*Discover, understand and **use** biological systems  
high-level NMR analytics*

# Three benefits of numares



1

Supporting patients to receive better cure based on effective diagnosis for their disease



2

Providing physicians better information for treatment decisions (unmet medical need)



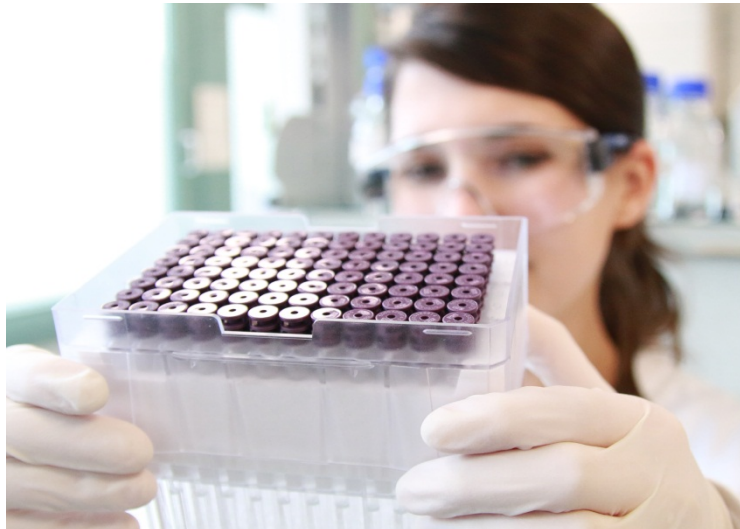
3

Providing Laboratories (hospitals / commercial) a new diagnostic platform for cost efficient, fully automated testing in routine operations

numares develops and sells new diagnostic tests, based on magnetic resonance spectroscopy (NMR) and specialized evaluation algorithm for metabolic profiles – offering also various possibilities in pharma development (e.g. clinical studies)

# numares HEALTH – company overview

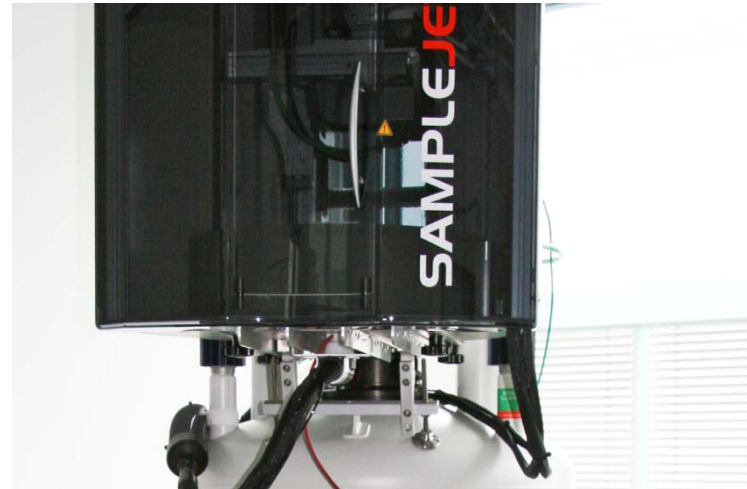
- numares HEALTH is an IVD system provider and IVD test manufacturer
- Founded 2004 as a spin-off from Regensburg University, Department of Medical Physics
- Strategic cooperation with worldwide leading laboratory group (customer) and NMR manufacturer Bruker Corp. (supplier)



- Up to today 12 successful installation of numares NMR instruments at US customer sites processing in 24/7 operations 2,500 to 3,000 patient samples a day
- Launch of the first CE-IVD dedicated NMR system and the first CE-IVD test for lipoproteins in cardiovascular diseases in 2014
- Several tests in oncology and nephrology are in the development pipeline

# numares HEALTH – infrastructure

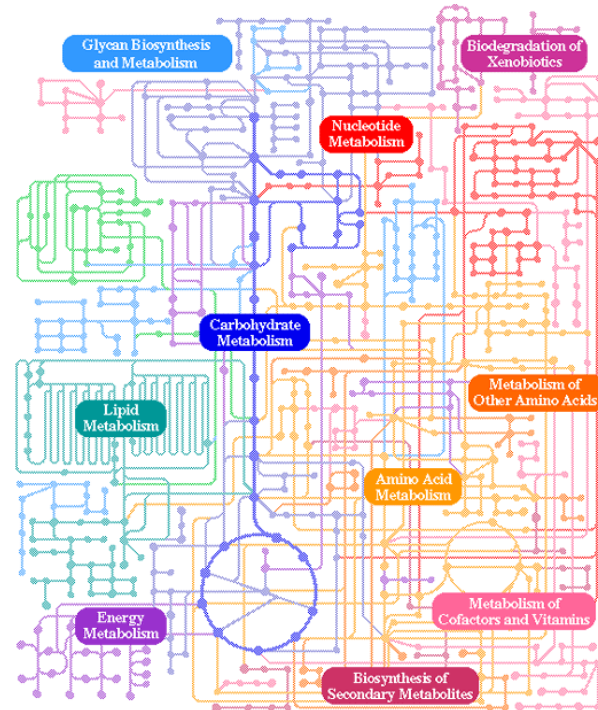
- 3 laboratories with GMP status as a testing laboratory for pharmaceuticals
- State-of-the-art NMR equipment for fully automated high throughput analyses
- Sample capacity of several hundreds of samples/day/platform



- 2013: certification acc. to EN ISO 13485 as an in-vitro-diagnostics (IVD) manufacturer
- Quality management systems, certified acc. to ISO 9001 and EN ISO 13485
- Interdisciplinary team of scientists and experts with a strong background in medicine, physics, (bio)informatics and (bio)chemistry

# The clue: Metabolism is a concert, a disease causes a disharmony

The numares NMR is like an advanced stethoscope for the physician.

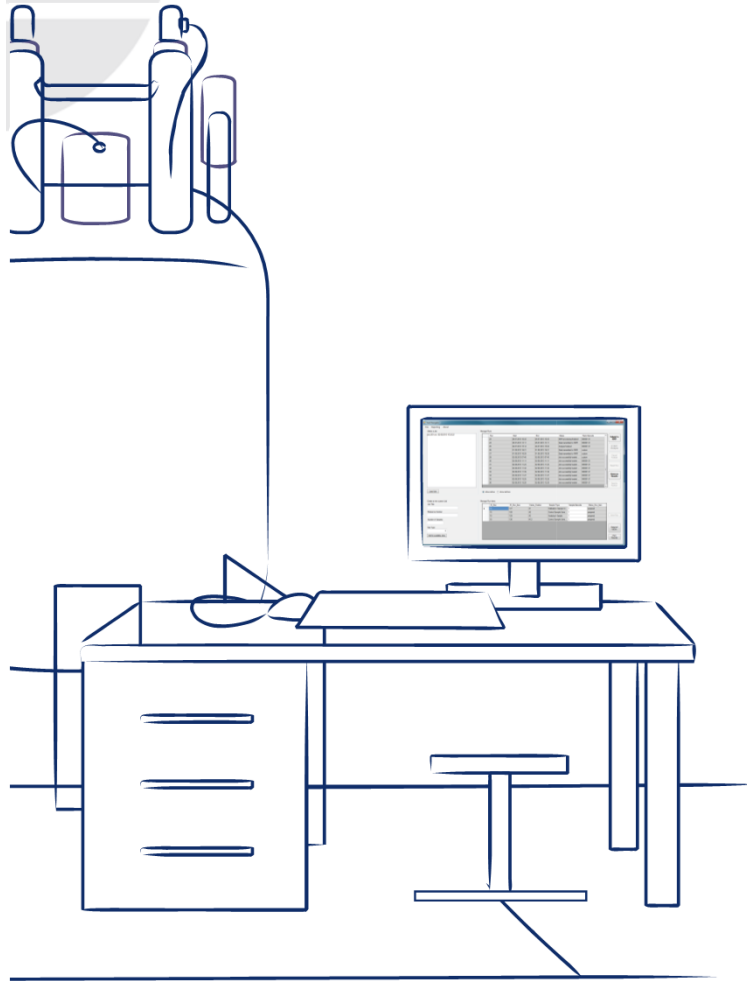


01100 5/31/04 Image source from KEGG

The human metabolism is the outcome of the activities of the proteome, it is like an orchestra playing beautiful music. A disease can be seen like a disharmony of tones. A metabolic profile can diagnose a disease. It is about the ratios of metabolites instead of absolute concentrations which are used so far as diagnostics.

# AXINON<sup>®</sup> test system

## AXINON<sup>®</sup> - an IVD and Life Science test system



- Easy access to metabolic data
- Meaningful results for medical questions
- Multi-testing flexibility
- Processing of different sample matrices
- Fully automated lab solution

# Business model - system provider for high throughput metabolic profiling

## IVD NMR instrument portfolio

- low/medium throughput 80/150 samples per day (\*)
- medium/high throughput 300/450 samples per day

## Service portfolio

- Two sites US and Europe
- NMR application specialists and IT experts

## AXINON® platform

- IVD NMR instrument
- Software suite for IVD tests

## IVD Test kits

- tubes / caps
- calibrator / controls

## IVD Test portfolio

- Lipoproteins
- Prostate Cancer (\*)
- Urothelial cancer (\*)
- Nephropathy (\*)
- Coronary artery disease (\*)
- Allograft rejection (\*)

**numares  
is a system  
business  
provider**

## Customer Service

- training
- repairs / maintenance

## Workflow integration

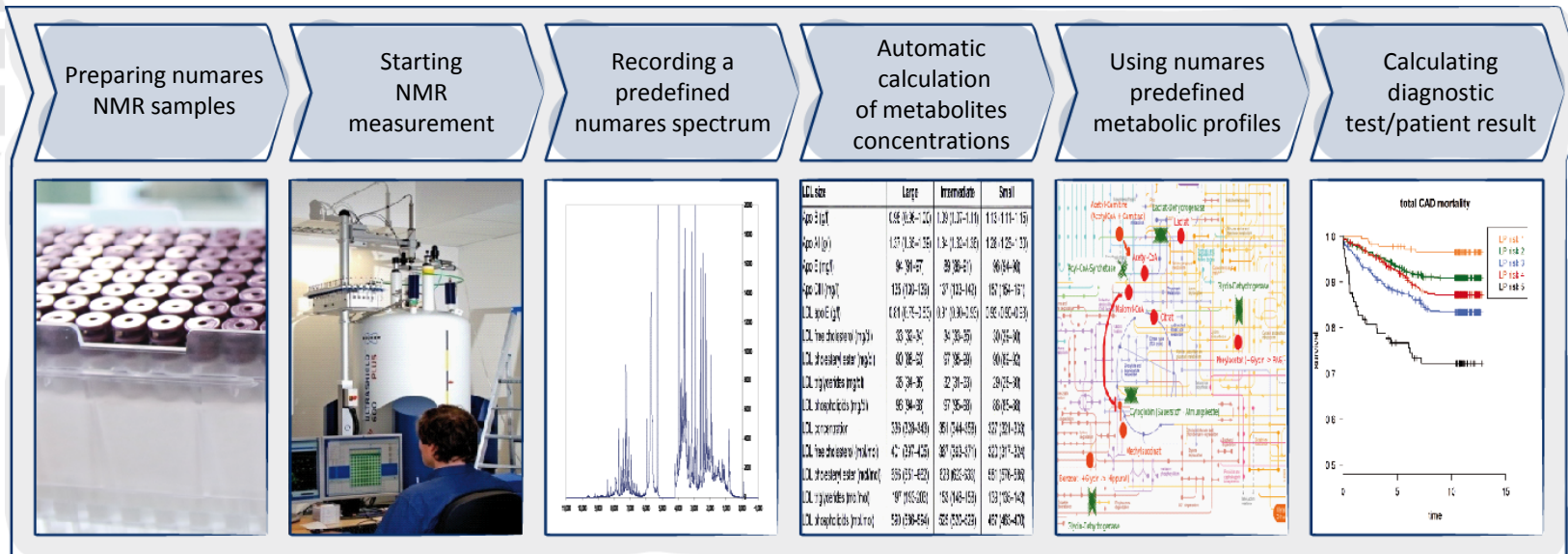
- LIMS / IT connectivity
- sample flow

Interface numares system / laboratory information system (LIMS) steered by individual bar-coded sample tubes to ensure data integrity

\* Under development, availability depends on regulatory clearance

# Test system workflow

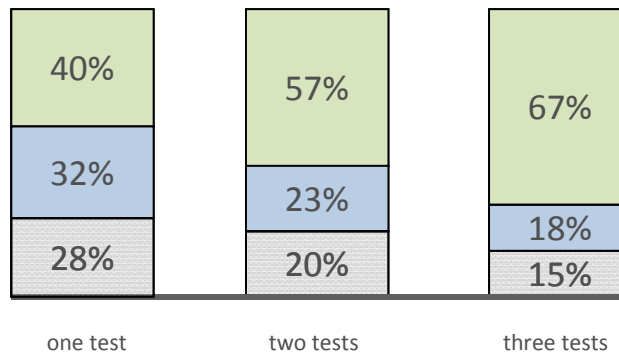
Laboratory workflow



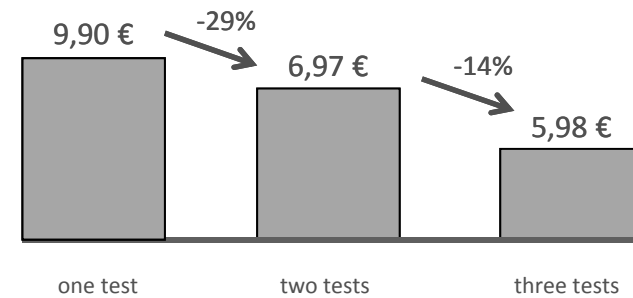
## numares AXINON test system, IP protected

Cost position

- Licence fee** for numares IP
- Consumable costs**
  - tubes
  - reagents
- Fix costs**
  - NMR instrument
  - infrastructure
  - labour costs



### Price per test / result (example)



# AXINON<sup>®</sup> lipoFIT<sup>®</sup> test system

## Advanced Lipoprotein subclasses profiling

- Particle concentration in lipoprotein (sub)fractions
- Mean particle sizes in VLDL, LDL and HDL fractions
- Cholesterol concentrations\* in lipoprotein fractions and subfractions
- Standard lipid panel (total cholesterol, triglycerides)
- Metabolic parameters (Glucose, Lactate, Alanine, Valine, Leucine, Isoleucine)
  
- Easy-to-operate system, minimal sample preparation
- Processing exclusively on the AXINON<sup>®</sup> IVD platform
- Cost-effective, time-saving, highly reproducible data

\*These parameters have been calibrated against several alternative methods.

# AXINON<sup>®</sup> lipoFIT<sup>®</sup> test system - applications

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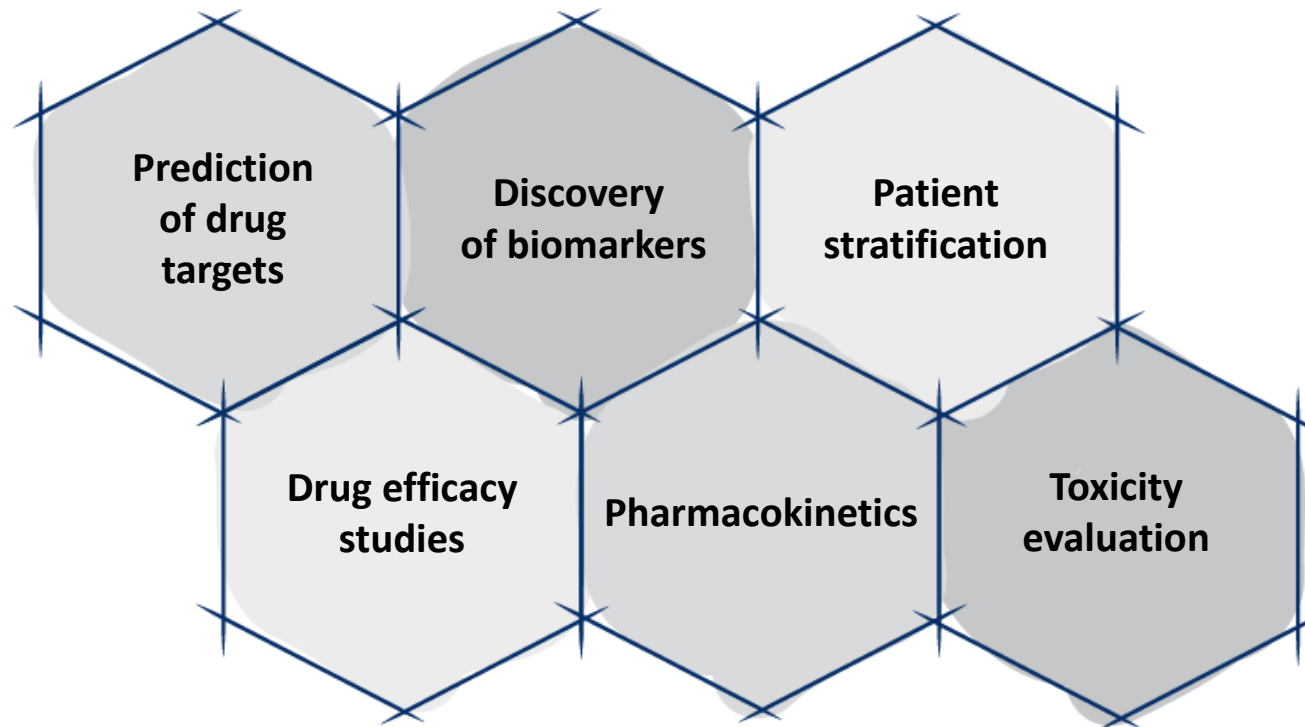
## Applications in pharma research & development

- Characterization of the therapeutic profile of new (lipid-lowering) drugs targeting cardiovascular disease (CVD) and metabolic disorders
- Patient stratification in clinical studies: improve candidate selection and reduce biological variability
- Advanced lipoprotein parameters as potential Companion Diagnostics
- Post-approval drug surveillance

# Our approach - reading metabolic profiles

numares offers you tests for (pharmaco-)metabolic and lipoprotein profiling.

numares' unique NMR expertise to read out the patient's metabolic state and use the information provided can boost discovery, development and monitoring of drug products.



→AXINON® - unique test system for several pharma development questions

# AXINON<sup>®</sup> test system - product pipeline

numares successfully applies metabolic and lipoprotein profiling combining high-level-NMR techniques with patented statistical methods for developing innovative test systems for IVD and research use.

## Coronary artery disease (CAD)



- CAD risk assessment based on lipoprotein subfraction analysis
- Several sample sets from different study cohorts analyzed
- Test system successfully established in clinical diagnostic routine use (US)

## Prostate cancer



- Test for staging/grading of prostate-cancer using urinary metabolomics
- Pilot study completed, data analysis in progress

## Renal allograft rejection



- Test for early diagnosis after NTX using urinary metabolomics
- Retrospective clinical trial and prospective study completed

## Nephrology



- Test for detecting impaired renal function
- Interpretation of metabolic profiles from urine



# numares – your contact partners



Dr. Volker Pfahlert

*Executive President, numares AG*

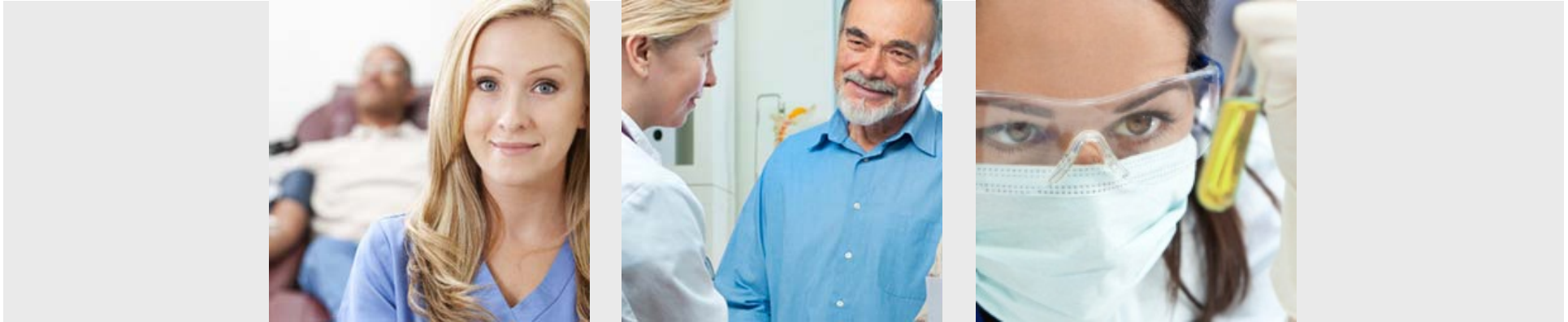
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**Thank you**



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