




**7TH SCIENCE TO MARKET, EAPB
MARCH 7 -8, 2016 - FRANKFURT
BIG DATA:
BIG BUSINESS – BIG FAILURES?**

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Sinfonie LSM
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BIO DEUTSCHLAND 1

Big Data: Big Business - Big Failures?



timoeiliott.com

"I think you'll find that mine is bigger..."

Sinfonie LSM
Dr. Martin Pöhlchen

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Growing Data Volumes in Diverse Healthcare Systems



Human genome/biological data
800 MB per full genome
15 PB+ in databases of leading institutes



Human proteome
160 Mil. data points (2.4 GB) per sample
3.7 TB raw proteome data in ProteomicsDB



Clinical information management systems
Often more than 50 GB



PubMed biomedical article database
23+ Mil. articles



Cancer patient records
160,000 at NCT Heidelberg



Medical sensor data
Scan of a single organ in 1s creates 10GB of raw data



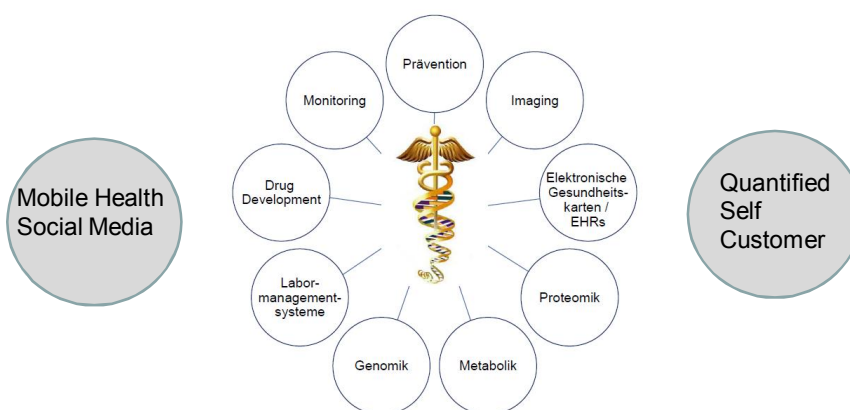
Prescription data
1.5 Bil. records from 10,000 doctors and 10 Mil. Patients (100 GB)



Clinical trials
Currently more than 30,000 recruiting on ClinicalTrials.gov

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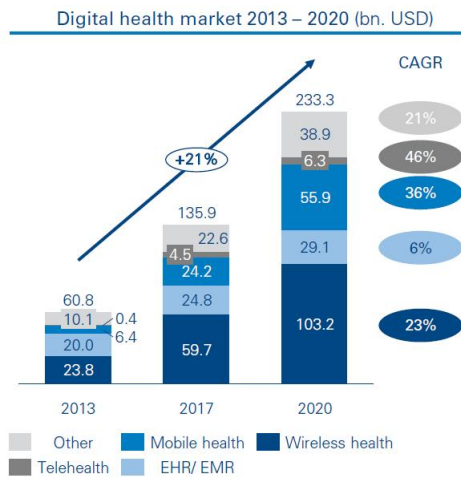
Big Data: Big Business - Big Failures?



- From closed expert systems to informed customers

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- The Digital Health Industry is expected to grow at an annual rate > 20%



Big Data: Big Business - Big Failures?

1. Stronger engagement of IT companies in Big Data in Life Science & Healthcare and e-Health than in the past
2. New business models and cooperations are created
 - Cooperations with new players, who connect R&D directly with the payor and the patient side
3. Enormous research budgets made available by the US, EU, China and other countries for Big Data topics

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1. Stronger engagement of IT companies in Big Data in Life Science & Healthcare than in the past (1):
 - **Verily, March 3rd, 2016: “Google of human systems biology”**
 - Andy Conrad, who heads up Verily—formerly known as Google Life Sciences—is working with a coalition of academic hospitals, physicians, universities, and patient advocates to bring medical information into one place.

Source: <https://www.fastcompany.com/3057455/verily-is-building-a-google-for-medical-information>, Future Genomics, March 3-4, 2016, La Jolla, US

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1. Stronger engagement of IT companies in Big Data in Life Science & Healthcare than in the past (2):
 - **Buzz: Apple plans to add 23andMe-style spit, May 8, 2015**
 - Apple has designs on the DNA sequencing sector. The tech giant is reportedly working with researchers to make 23andMe-style DNA sequencing spit kits part of ResearchKit, the platform that turned every iPhone user into a potential study participant.

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1. Stronger engagement of IT companies in Big Data in Life Science & Healthcare than in the past (3):
 - **IBM launches new health unit, teams up with Apple, J&J, Medtronic, April 13, 2015**
 - IBM creates new company in Boston with 2,000 employees. Analysis of 700 million i-phone users. Previously IBM bought Explorys und Phytel to strengthen healthcare data analytics

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2. New business models are created (1):

Cooperations with new players, who connect R&D directly with the payor and the patient side.

 - **Quintiles tweaks Apple's ResearchKit for use in biopharma-sponsored trials, November 16, 2015**
 - Quintiles has made changes to Apple's open-source ResearchKit framework. The CRO made the enhancements--the code for which it released on the GitHub repository--to make Apple's platform more suitable for the trials it oversees. "We want to be the leader when it comes to collaboration with technology giants such as Apple," a spokesperson for Quintiles explained.

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2. New business models are created (2):

- **Flatiron Health, the leader in cloud-based oncology software, today announced a Series C fundraising round totaling \$175 million, led by Roche, Jan 6, 2016**
- “Google Series C Round to Further Bolster its OncologyCloud Software Platform for Providers and Accelerate Personalized Medicine. OncoEMR , the industry-leading electronic health record for oncology with an integrated patient portal and claims system”

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2. New business models are created (3):

- **Flatiron raises \$130M in Google-led round, buys EMR business, May 11, 2014**
- Google Ventures' reported \$100 million investment in oncology Big Data startup Flatiron Health came to fruition this week. And the deal is even bigger than early reports suggested, with Flatiron raising \$130 million and buying electronic medical record business Altos Solutions.

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2. New business models are created (4):

- **Novartis Pharmaceuticals collaborates with Qualcomm in digital innovation with the Breezhaler(TM) inhaler device to treat COPD, Jan -5, 2016**
- “The collaboration further supports Novartis' focus to empower patients making it easier for them to manage their own chronic disease by having near real time access to their own data on inhalation use.”

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2. New business models are created (5):

- **AbbVie partners with Google's Calico on \$1.5B R&D operation focused on aging, September 3, 2014**
- AbbVie Pharmaceuticals has followed up today with a plan to partner with Google's closely watched biotech upstart Calico on a new research operation that will cost up to \$1.5 billion to get started.

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3. Governmental research budgets made available by the US, EU, China and other countries for Big Data topics (1)
 - **Horizon 2020: IMI2, Big Data For Better Outcomes (12/15)**
 - Provide a platform and resources for defining and developing enablers of the outcomes transparency evolution together with patients, payers, physicians, regulators, academic researchers, healthcare decision makers, etc. key enablers:
 - definition of outcome metrics; protocols, tools to access high quality data
 - methodologies and analytics to drive improvements, and
 - digital and other solutions that increase patient engagement

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3. Governmental research budgets made available by the US, EU and other countries for Big Data topics (2)
 - **“Medizininformatik” (November 16th, 2015, BMBF)**
 - Improve patient care and research via innovative IT systems
 - Such IT systems should enable usage of data from healthcare, biomedical and clinical research independent from locations and academic institutions
 - 1st deadline: 31.3.2016

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4. Other examples for new alliances and melting of industry barriers
 - Venture Capital fund cooperates with Health Insurance Company
 - Samsung invests heavily in Biosimilars and Industry 4.0
 - Google cooperates with Novartis on contact lenses for continuous glucose monitoring
 - Pfizer cooperates with Kaiser Permanente
 - Generali offers insurance discounts for compliance to e-health monitoring

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- **Use Case (1) ASCO: Health Information Technology Platform: CancerLinQ**
- “Big data is about to get bigger. CancerLinQ is assembling vast amounts of usable, searchable, real-world cancer information into a powerful database. This national initiative was inspired and informed by the cancer experts at [ASCO](http://asco.org), so it's not merely an exercise in IT”
- <http://cancerlinq.org/> (ASCO & SAP), May 30, 2015

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- **Use Case (2): Infectious Diseases and Antibiotics**
 - Antimicrobial resistance (AMR) is a real and immediate Global threat. The damaging effects caused by resistant bacteria already claim 50,000 lives per year in Europe and the USⁱ. Future predictions of the impact of unresolved AMR have described 10 million additional deaths per year by 2050, resulting in a cumulative cost to the global economy of up to one hundred trillion US dollars (£64tn).
 - For these reasons AMR is a national priority for many Governments, with some ranking AMR alongside climate change, catastrophic terrorist attack, and pandemic
- i) Jim O'Neill, 2015, Tackling a global health crisis: initial steps, <http://amr-review.org/sites/default/files/Report-52.15.pdf>
 Cabinet Office, 2015, National Risk Register of Civil Emergencies, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419549/2015-NRR-WA_Final.pdf

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- **Use Case (2): Seoul National University Hospital (SNUH)**
- Clinical indicator analysis powered by the SAP HANA, SNUH dramatically reduced the unnecessary use of antibiotics
- Third-line preoperative antibiotic use dropped to zero
- The duration that antibiotics were administered to patients before surgery fell from six days to one
- Reduced waiting times for complicated data queries from more than 1 hour to less than 5 seconds

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- **Use Case (3) Health Policy: National Rural Health Mission in India**
- A pilot program for 270 million school children to start a lifetime of data collection, using mobile tablets for data entry and cloud storage for all health data.
- **Goal:** Determine the need for medical support, prevent epidemics, and provide analysis capabilities to aid in the understanding of health trends across the population.
- Currently > 60.000 children enrolled

Source: <http://www.forbes.com/sites/sap/2014/04/10/health-in-rural-india-will-never-be-the-same>, Collaboration between Indian Ministry for Health and SAP

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- **Use Case (4) Data-gathering implantable chips to be tested in schizophrenia trial, November 13, 2015**
- Although wearables have yet to establish themselves as a mainstream clinical trial technology, some research teams are already looking to the next big thing: implantables.
- Pierre Fabre has moved itself to the forefront of the field by striking a deal to test a chip in an ongoing Phase II clinical trial of a schizophrenia drug in development
- The Swiss Federal Institute of Technology in Lausanne (EPFL) is behind the technology being tested by Pierre Fabre. At the center of the technology is a biosensor chip, which EPFL has designed to track pH, temperature, blood glucose levels and other indicators of the homeostasis of the body, while also keeping tabs on the concentration of any drugs administered to the individual.

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■ Use Case (5): Respiratory Diseases

- Rationale: Comorbidities contribute to disease severity and mortality in patients with chronic obstructive pulmonary disease (COPD). Previously Comorbidities have been studied individually and were mostly based on self-reports. The coexistence of objectively identified comorbidities and the role of low-grade systemic inflammation in the pathophysiology of COPD remain to be elucidated.
- Objectives: To cluster 13 clinically important objectively identified comorbidities, and to characterize the comorbidity clusters in terms of clinical outcomes and systemic inflammation.

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■ Use Case (5): Clusters of Comorbidities Based on Validated Objective Measurements and Systemic Inflammation in Patients with COPD

- A total of 97.7% of all patients had one or more comorbidities and 53.5% had four or more comorbidities. Five comorbidity clusters were identified: (1) less comorbidity, (2) cardiovascular, (3) cachectic, (4) metabolic, and (5) psychological.
- Low-grade systemic inflammation is mostly comparable among comorbidity clusters. This shows that the presumed association between systemic inflammation and comorbidities in patients with COPD is more complex than assumed at present. Increasing knowledge on the interactions between comorbidities contributes to strategies for prevention or improved treatment.
- Collaboration between Maastricht University Medical Centre (Netherlands), CIRO (Netherlands), Biomax Informatics (Germany), Viscovery Software GmbH (Austria), Astra Zeneca (Sweden), Vanfleteren et al., AMERICAN J RESP & CRIT. CARE MED. VOL 187 2013)

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- **Use Case (6): Boston Children's Hospital to Tap IBM Watson to tackle rare paediatric diseases, Friday, 13 Nov 2015**
- IBM and Boston Children's Hospital has announced that they intend to collaborate to apply IBM's Watson cognitive platform to help clinicians identify possible options for the diagnosis and treatment of rare paediatric diseases.
- In an initial project focused on kidney disease, Watson will analyse the massive volumes of scientific literature and clinical databases on the Watson Health Cloud to match genetic mutations to diseases and help uncover insights that could help clinicians identify treatment options

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- **Use Case (7): Disease Focus**
- Cardiovascular Diseases
- Respiratory Disease
- Infectious Diseases
- Multiple Sclerosis, Autoimmune Diseases
- CNS Diseases, incl. Alzheimer, Dementia, Depression, etc
- Interaction Studies – New correlations, New Insights
- Impact on chronic diseases expected to be higher

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Big data in biomedicine

Eric Bender
Nature 527, S1 (4 November 2015)

Q&A: Mark Caulfield National genomics

Claire Ainsworth
Nature 527, S5 (4 November 2015)

Collaborations: Mining the motherlodes

Katherine Bourzac
Nature 527, S8-S9 (4 November 2015)

Mobile data: Made to measure

Neil Savage
Nature 527, S12-S13 (4 November 2015)

Perspective: Sustaining the big-data ecosystem

Philip E. Bourne, Jon R. Lorsch & Eric D. Green
Nature 527, S16-S17 (4 November 2015)

Big data: The power of petabytes

Michael Eisenstein
Nature 527, S2-S4 (4 November 2015)

Proteomics: High-protein research

Neil Savage
Nature 527, S6-S7 (4 November 2015)

Cancer: Reshaping the cancer clinic

Charlie Schmidt
Nature 527, S10-S11 (4 November 2015)

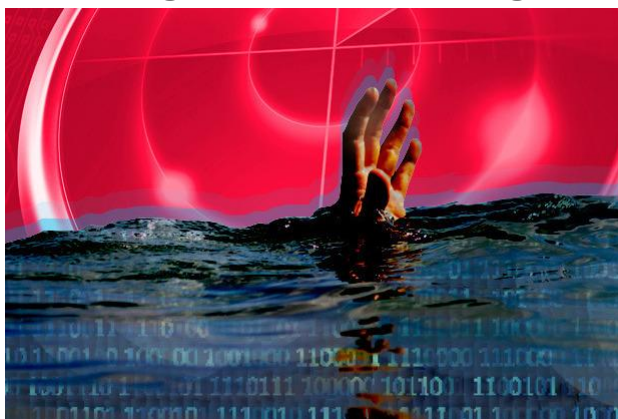
Deep phenotyping: The details of disease

Cathryn M. Delude
Nature 527, S14-S15 (4 November 2015)

Q&A: Perry Nisen

Better insights, better drugs
Eric Bender
Nature 527, S18 (4 November 2015)

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Source: Thinkstock

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- **Study reveals that most companies are failing at big data, Nov 10, 2015**
- Research from PwC and Iron Mountain reports some surprising statistics
- The study found that while 75 percent of business leaders from companies of all sizes, locations and sectors feel they're "making the most of their information assets," in reality, only 4 percent are set up for success.
- Overall, 43 percent of companies surveyed "obtain little tangible benefit from their information," while 23 percent "derive no benefit whatsoever," according to the study.
- 75% of organizations surveyed lack the skills and technology to use their data to gain an edge on competitors. 20% haven't employed a data analyst

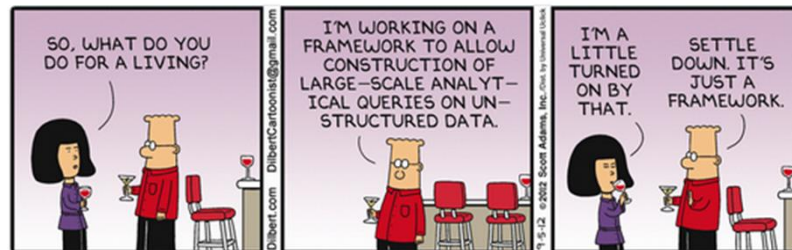
Source: <http://www.cio.com/article/3003538/big-data/study-reveals-that-most-companies-are-failing-at-big-data.html>

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- **Study from Moorhouse (FTSE250) showed only 11% of organisations believe they are leveraging big data effectively to inform their strategic**
- "First the industry promised untold benefits, we then moved on to scepticism and we're now at the point of seeing the first practical wins," says Matt Davies, Head of EMEA Marketing at Splunk
- "We're only at the beginning of the big data story and the next couple of years should see the industry focusing on the value and delivering on that early promise of big data." Giles Slinger, Director at data analytics firm Concentra
- It's a buzz-phrase, it's a popular hashtag on social media, and it looks great on a CV. Big data is so 'zeitgeisty'

Source: By [Jamie Carter](#) January 20, 2016 [World of Tech](#)

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- **Validity, Veracity in Big Data: 2014 Warning Letter Trend: Increasing Number of Data Integrity Observations**
- The audit trail functions disabled at time of inspection
- “Unofficial” testing of samples, results discarded, and results from additional tests reported as results of record
- Discarded hard copy records found during inspection
- Testing into Compliance
- Failing results not included in official lab control records, and not reported or investigated
- Batch records signed by individuals who did not perform the review
- Activities that were not performed were recorded in batch records

Source: FDLIA Conference, April 2015, Deloitte & Touche LLP, Washington, DC, USA

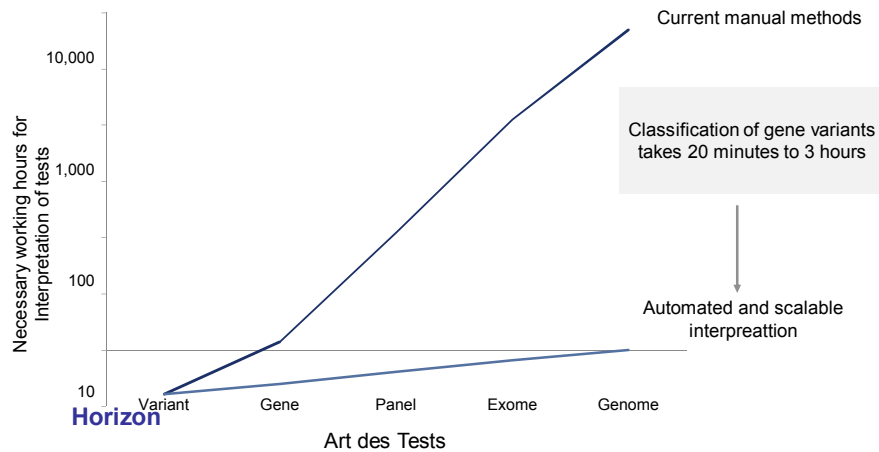
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- **Not Identifying Business Objectives**
- Using big data for the sake of using big data is a surefire ticket to nowhere
- Identify a clear business objective that you want to achieve as a company
- Focus on why you want to solve a Big Data task
- Do not focus on how you solve a Big Data task

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- **Relying Too Much on the Data**
- Big Data project that relies solely on the numbers is likely to fail.
- Prove Anderson wrong: Anderson, Chris. 2008. "the end of theory: the data deluge makes the scientific method obsolete." *Wired Magazine*.
- Transformation from Big Data to Smart Data not in line with Anderson

Data analysis not in line with lab analysis



Challenges for Big Data (1)

- Insufficient and already outdated E-Health legislation in Germany
- Missing Transparency Directive for health insurance data and usage for R&D similar to Clinical Trials Directive and other EU transparency guidelines
- Missing international, national and even regional harmonisation concerning data security and public acceptance
- Convergence of legal regulations for „Medical Records“ in the areas of E- and „Mobile Health“ as well as new regulations for data exchange regarding „Medical Records“ in hospitals, etc. (for example for research purposes / Biotech R&D)

Challenges for Big Data (2)

- Monolithic data silos and information gaps between biotech, pharma, CROs, patients and healthcare providers and payors
- Rising costs of interpretation of data versus wet lab costs and missing reimbursement
- Missing technical standards for efficient exchange of data among different industries
- Regulatory issues (see FDA) in terms of data veracity and data security
- Technical challenges of semantic Web 3.0

Challenges for Big Data (3)

- Not enough well educated data scientists and executives to manage and implement Big Data analytics at the intersections of IT, healthcare and life science
- Public perception and schizophrenic user behaviour concerning Quantified Self Movement and data security
- Industry transformation in healthcare and life science from expert systems to customer oriented solutions

Summary

- New business models and cooperations with other industries and patients are mandatory for success
- Big return on Big data investments takes more time as „Big“ success is linked to development time lines of novel products/services in Life Science and Healthcare
- Immediate returns stem from finance, processing and logistics
- Convergence of data protection and data security legislation necessary
- Veracity and Validity of data in Big Data applications and outdated data silos remain a challenge

Experts AG Bio-IT & Big Data

Dr. med. Eric Aichinger , Biotype Diagnostic GmbH	Dr. Brigitte Obermaier , Eurofins Medigenomix GmbH
Marian Arning , Osborne Clarke	Vincent Pearson , Livatek GmbH
Fabian Böttger , Baker & Mc Kenzie	Frank Pflüger , Baker & Mc Kenzie
Andrew Daniel , Certara	Marco Pietschmann , GATC Biotech AG
Dirk Distelrath , KPMG AG	Dr. Martin Pöhlchen , Sinfonie Life Science Management GmbH
Wirtschaftsprüfungsgesellschaft	Dr. Armin Rath , Shionogi GmbH
Dr. André Domin , Technologiepark Heidelberg GmbH	Dietmar Rescheleit , Sacura GmbH
Dr. Timo Ehmann , Weitnauer Rechtsanwälte	Dr. Maïke Rochon , BioRegioN GmbH
Dr. Volker Fitzner , PricewaterhouseCoopers AG WPG	Dr. Josef Scheiber , BioVariance
Dr. Frank Götz , Biotype Diagnostic GmbH	Karlheinz Schmelig , Creathor Venture Management GmbH
Dr. Bettina Hädrich , QIAGEN GmbH	Dr. Andreas Schmidt , AyoxxA Biosystems GmbH
Dr. Jens Hellwage , InfectoGnostics	Stefan Schrettle , PricewaterhouseCoopers AG WPG
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Thank you very much for your attention!

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Fördermitglieder der BIO Deutschland und Partner sind:



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