



# European Biotechnology

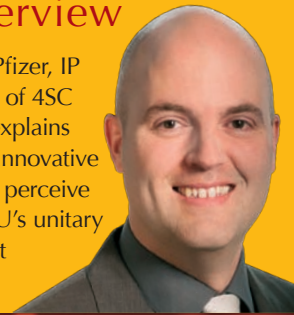
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Life Sciences and  
Industry **Magazine**

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## Interview

José Pfizer, IP  
Head of 4SC  
AG, explains  
how innovative  
SMEs perceive  
the EU's unitary  
patent



**FREE EXCERPT**

## Big Data War

# The Bytes of Cancer

### Neurodegeneration

Drug developers are hunting for a cure to Huntington's disease

### Archaea

Are these extremophiles the solution to the energy crisis?

### Bioeconomy

Insect protein – the Next Big Thing in food and feed?

### Biomufacturing

Latest R&D and packaging trends for CROs, CMOs & CPOs

### Drug Substance

- Cell Culture
- Microbial

### Development

- Own CHOBC® platform

### Drug Product

- Fill&Finish
- Lyophilization

### Products

- mABs
- New AB formats
- Proteins

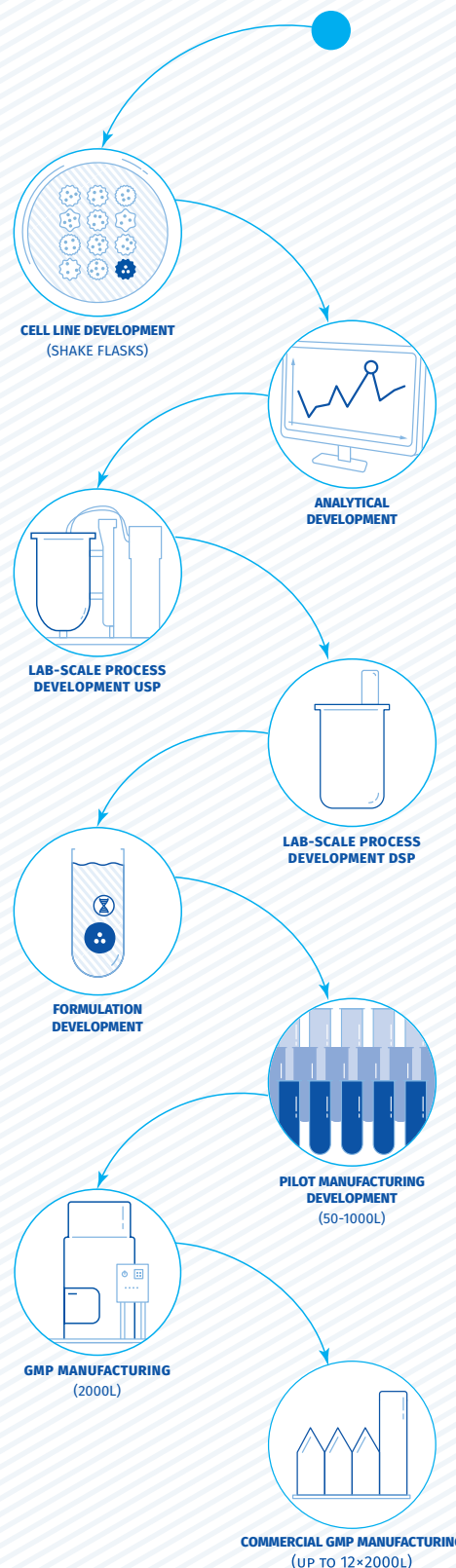
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**CPH:** STAND NO 6.0D.30  
Frankfurt, 24-26 October

**Bio Europe:** BOOTH NO 70  
Berlin, 6-8 November

## YOUR MODULAR ONE-STOP-SHOP

FOR BIOPHARMACEUTICALS



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## COVER STORY



## AI and cancer – the modern data wars

Big Data is changing the way doctors make decisions, and redefining privacy. Should companies be allowed to lock up patient information in proprietary databases? Or should it be open access? Does medical data like a tumour's DNA sequence belong to the patient, or should it be pseudonymised for use in studies aimed at curing the disease? And not least – how quickly will cognitive systems really make a difference in outcomes? A lot of money is at stake in the field, as well as people's lives.

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NEURODEGENERATION

## Curing Huntington’s

It slowly but relentlessly destroys your body and your mind, and there’s nothing doctors can do to stop it. At least, until now. 25 years after an American scientist discovered the genetic mutation that causes Huntington’s disease, medical research is finally beginning to catch up. An ongoing trial is attempting to stop the disease in its tracks. And one day a gene therapy solution might effectively cure it.



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BIOECONOMY



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## Green methane

They live in some of the most extreme environments on Earth, including hydrothermal vents and geysers. Archaea are fascinating microorganisms that seem to have changed little since the dawn of life. Now they could help us solve one of our most pressing modern problems – how to store excess power from renewable sources.



Pictures: Wikimedia Commons/James St., John (top), visualspace /istockphoto.com (middle), Adenis (bottom)

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EDITORIAL

## Digital reshape

Digitalisation is set to become the buzzword of 2017. Whether you’re talking about patient selection for clinical trials, cancer therapy decision support, customer relations, direct-to-consumer advertising or even supply chain management – everyone is convinced digitalisation is the key to efficiency. For some, however, the word is an empty one. Recently one German biotech CEO stressed that “it’s just a tool, not the solution”. In other words, don’t expect it to cure cancer.

On p.18, our cover story shows what kind of value creation digital data from cancer mutations and treatment outcomes could contribute in the long run to more personalised therapies. Although there’s hype and PR in overselling computational correlation analyses, researchers from companies and hospitals agree that it will one day improve prognosis and decision support. A big issue, though, is access to results.

Looking forward to the CPHI and BIO-Europe, we’ve addressed the topics that are most relevant to the sector, among them the EU unitary patent (see p. 6–8), the latest outsourcing trends in biomanufacturing, pharma packaging, and contract research, along with the latest news from the growing bioeconomy sector. A new EU strategy is being drafted (p.15) while EU companies are working to replace GM soy protein with insect-based feed (p. 90). Enjoy!



Thomas Gabrielczyk  
Editor-in-Chief



Finding driver mutation patterns in tumour genomes could turn the fields of AI/bioinformatics into a stethoscope for the 21<sup>st</sup> Century

# Cancer data: A dive into the depths

**CORRELATION SCIENCES** As Big Data analytics begin to inspire medical decisionmaking, companies and scientists have gone to war over access to data derived from patient biopsies. Cancer profiling is a seminal situation. While some companies are seeking to profit from approaches to advanced mutation analysis, researchers are vociferous in demanding open access to proprietary databases behind company firewalls.

According to William – “call me Bill” – Kassler, human decisions are anything but perfect. “But machines can debug that,” stresses the Deputy Chief Health Officer & Lead Population Health Officer at IBM Watson Health in Boston. Speaking last summer at the Forum Science & Health conference in Munich, the ex-CDC policy advisor and former Medicare expert for value-based drug pricing predicted that cognitive computers would be the Next Big Thing in personalised medicine. Intelligent machines such as IBM Watson, he insisted, could learn rapidly. “Within just four years, Watson scaled down its error rate from over 40% to 5% in recognising language. And that’s just the beginning,” says Kassler. What if that power was turned to unravelling hidden patterns in tumour genomes?

## Why data analytics could transform biopharma

The first applications for these kinds of learning machines and algorithms are currently surfacing in personalised medicine, particularly in the highly lucrative field of cancer. Kassler knows that identifying drug responders to a growing number of cancer combination therapies and immunotherapies is still quite limited. He also knows that cash-strapped health systems want to switch to value-

based pricing by limiting reimbursement of costly targeted cancer therapies or immuno-oncological treatments to patient groups that have a proven benefit. It’s no secret that current Companion Diagnostics (CDx) are not designed for cancer mutation pattern detection. But because cancer-promoting effects are dependent on surrounding genes and an individual genomic context, AI-directed genome mining is currently *en*

*vogue* in the sector. In 2013, IBM began promoting Watson as a ‘best treatment’ detector. The claim was based on mining cancer genomes and corresponding treatment data stored in Electronic Medical Records (EMRs). According to Kassler, Watson’s learning algorithms – which he brands “artificial intelligence” – could assist physicians on two fronts:

- collecting and interpreting the flood of medical discoveries from papers, slides, clinical trials, and other data
- finding unrecognised patterns in real-world data, including relevant mutations in cancer genomes, prognostic patterns in EMRs, images, lifestyle data from fitbits, etc.

Experts like Roger Schank say that Watson simply “correlates data”, and that this ability is subsequently sold as ‘AI’ for marketing purposes. He stresses that an ability to sift through a large amount of data doesn’t define intelligence. The data-mining approach, however, has attracted Big Data analytics majors like IBM, Google, its spin-out Verily, Microsoft and a growing number of high-tech SMEs. That’s because it can generate exactly the data needed by payors to [...]

➤➤ Read the full story in the printed issue.



**JOSH LAUER** Lifecycle Leader, Foundation Medicine (FMI) at Roche

? How can Roche help to expand FMI’s capabilities?

! We have to build on FMI international traction by leveraging on presence in many countries. We have already launched the service in 12 countries. We look forward to bringing it to every market.

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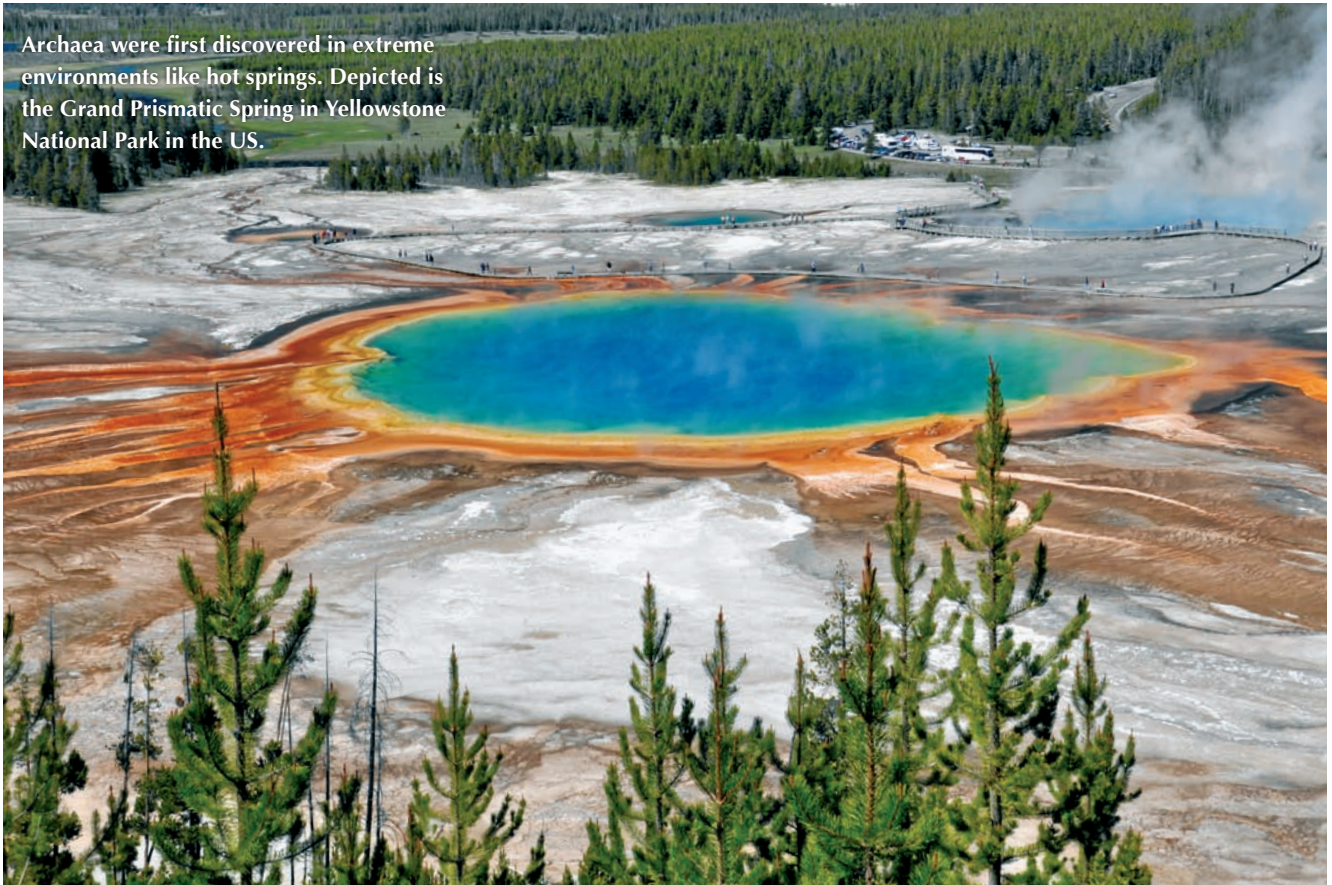
# The hunt for a cure to Huntington's

**GENETIC DISEASES** It's a disease that often strikes people in the prime of life, slowly destroying control over body, mind and personality. It inevitably kills the patient, but usually only after at least a decade of suffering. The underlying cause of Huntington's disease – a dominant mutation on Chromosome IV – was discovered almost 25 years ago. Now the first trials to target the condition at its source have begun. Chances of finding a cure have never been more realistic.

»» Read the full story in the printed issue.

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Archaea were first discovered in extreme environments like hot springs. Depicted is the Grand Prismatic Spring in Yellowstone National Park in the US.



# Hot guys in the pool rescue sustainability

**BIOLOGICAL METHANATION** The renewable energy sector is ramping up in a major way, but a host of infrastructure issues still need to be solved. One is that supply at times now outstrips demand, but there's no way to store excess power. Turning it into an easy-to-store, energy-rich source like methane could solve the problem. A pivotal aspect of 'power-to-gas' technology harnesses some tiny helpers usually found in some of the most extreme regions on the planet.

>> Read the full story in the printed issue.

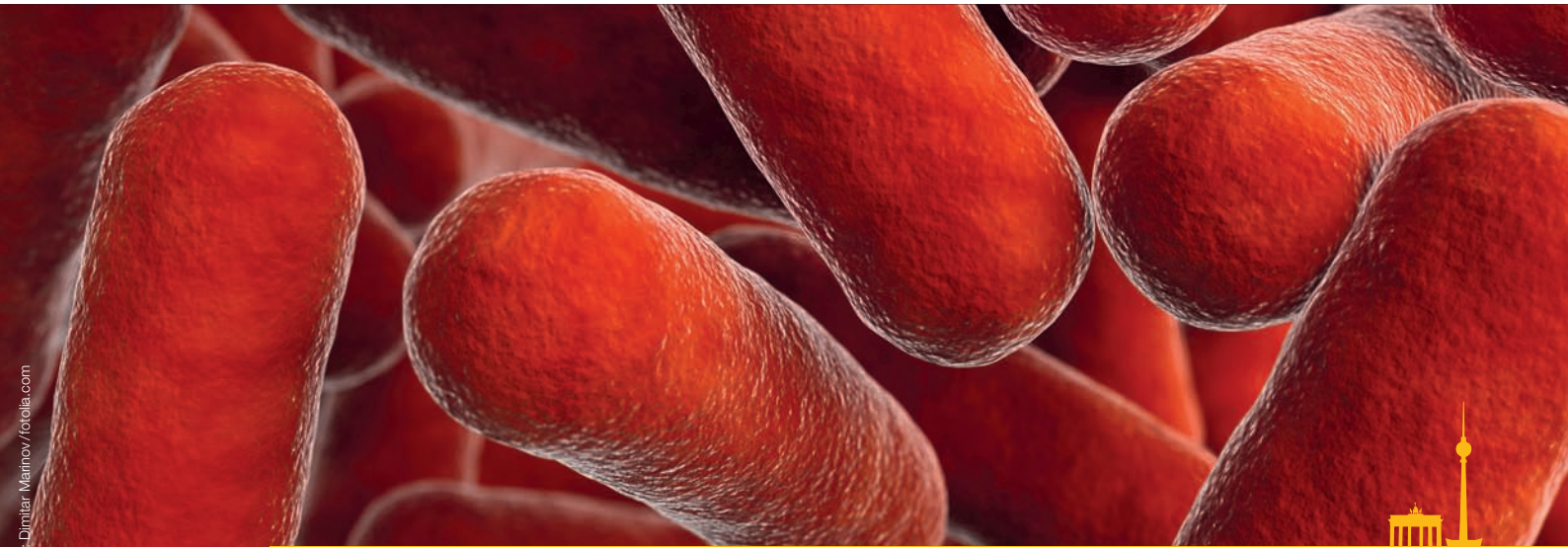


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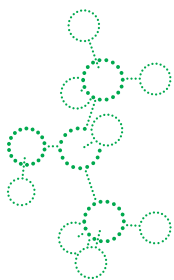
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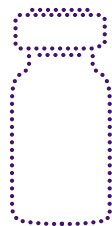
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