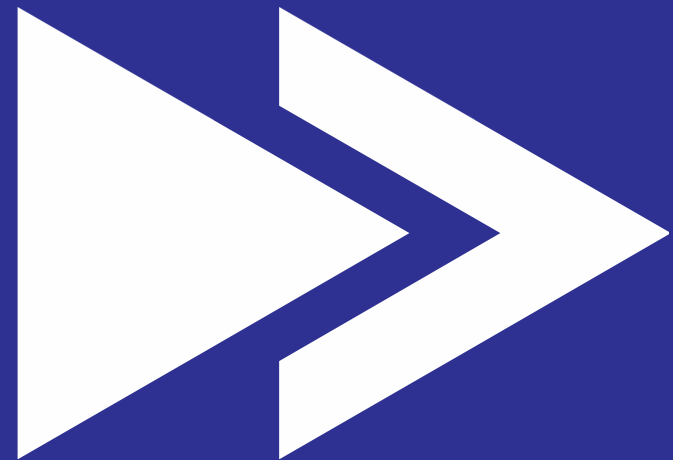


# Webinar Digital Healthcare - Regulatory Outlook and Key Events in 2017:

## The German eHealth Environment



Sebastian Zilch

German Association of Healthcare IT Vendors

09 March 2017



## OVERVIEW

1. German Association of Healthcare IT Vendors
2. conhIT – Connecting Healthcare IT
3. Recent German eHealth Legislation & Telematics Infrastructure
4. European Regulation
5. Outlook

# 1

## GERMAN ASSOCIATION OF HEALTHCARE IT VENDORS (BVTG) - MEMBERS



# 1

## GERMAN ASSOCIATION OF HEALTHCARE IT VENDORS (BVTG) - MISSION

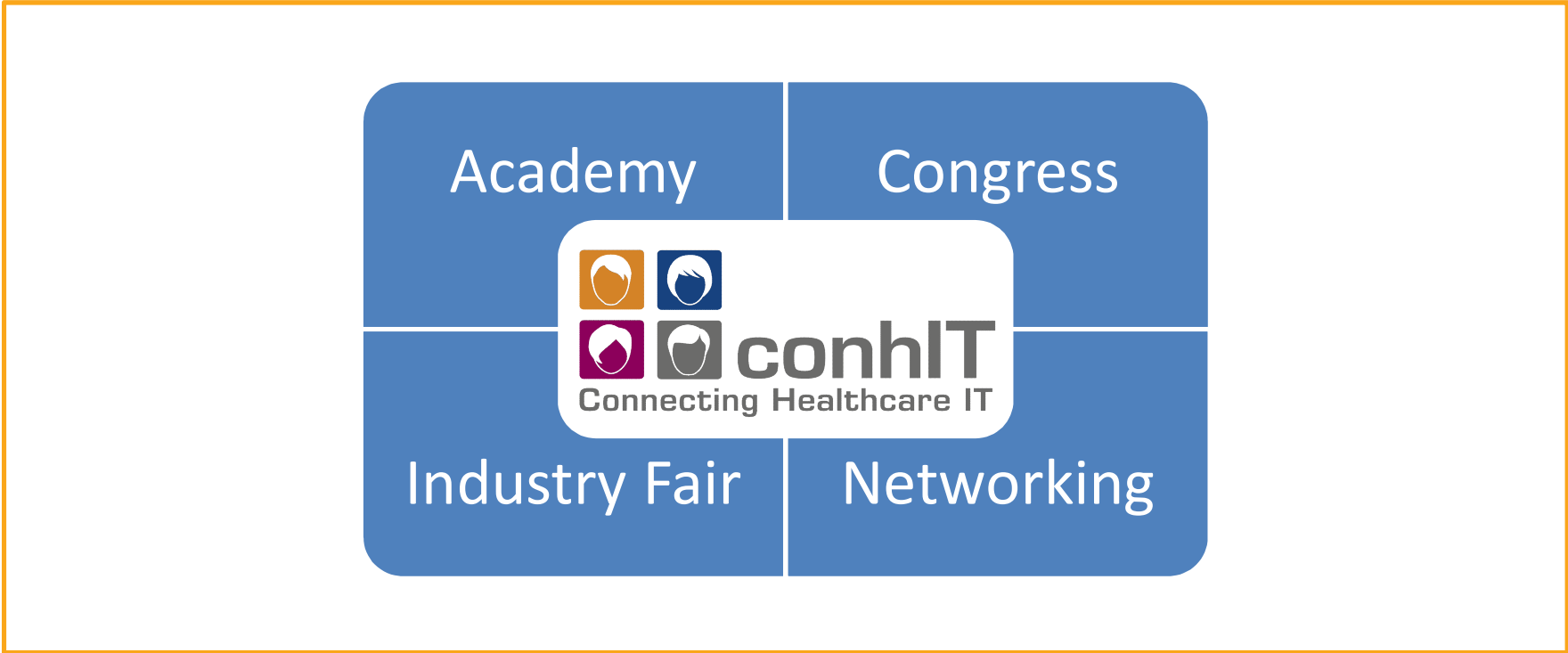


- ▶ Represents the leading providers of healthcare IT in Germany
  - ▶ 90 percent of the German health IT market
  - ▶ 70 percent of member companies operate internationally
- ▶ Established partner for the government and the institutions and organizations of healthcare providers and health insurance companies
- ▶ Our Goals are:
  - ▶ Establish healthcare IT in all areas of medical care
  - ▶ Be in close dialog with all actors of healthcare IT
  - ▶ Advance interoperability and international standards
  - ▶ Ensure competitiveness of the industry
  - ▶ Inform the public about the market

2

CONHIT 2017

» bvitg

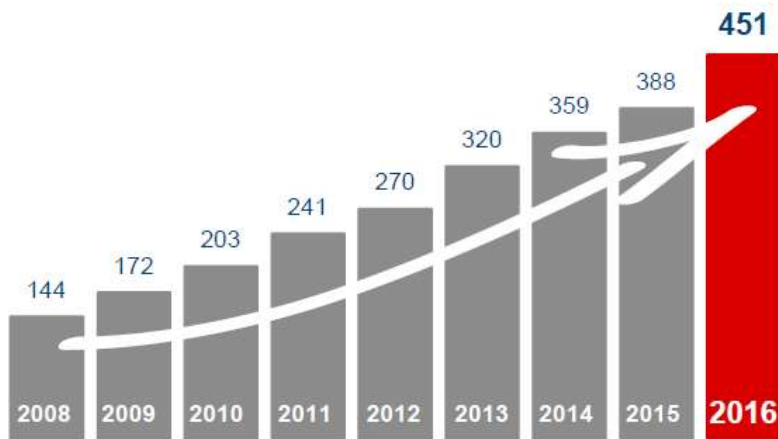


# 2

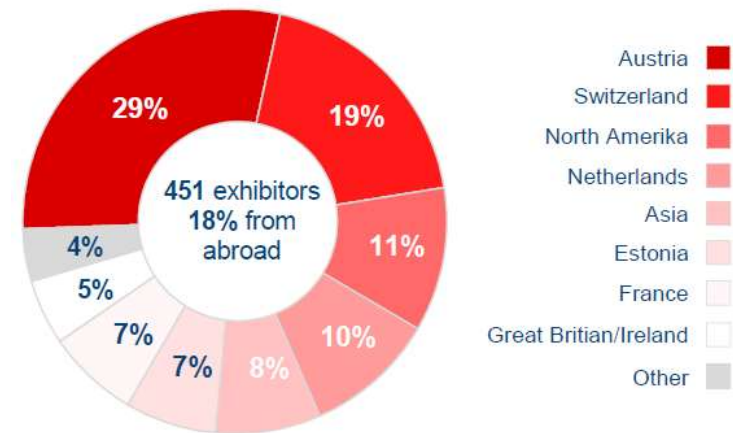
## CONHIT 2016 EXHIBITOR'S



### Exhibitor figures



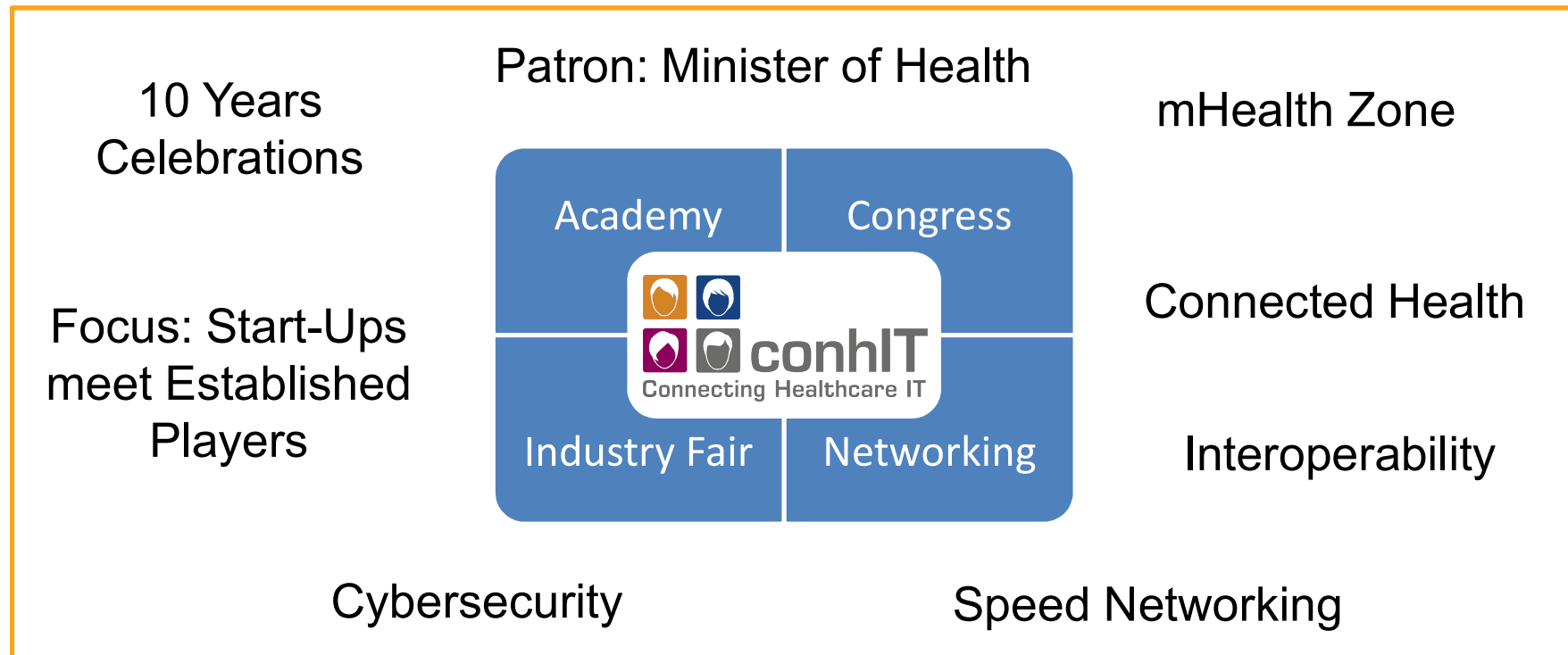
### International exhibitors



Source: conhit exhibitor's survey 2016

# 2

## CONHIT 2017 HIGHLIGHTS



# 3

## RECENT GERMAN E-HEALTH LEGISLATION



- ▶ IT-Security Act 2014
  - ▶ Overall increased coordination and reporting requirements (similar to NIS-Directive)
  - ▶ Critical infrastructures in healthcare; mostly hospitals (30.000 cases p.a.)
  - ▶ bvitg involved in defining security standard for the healthcare sector (2018)
  
- ▶ eHealth Act 2015
  - ▶ Focus on *Telematics Infrastructure* and attached services
  - ▶ Interoperability Registry (June 2017)
  - ▶ Electronic Patient Record (2018)

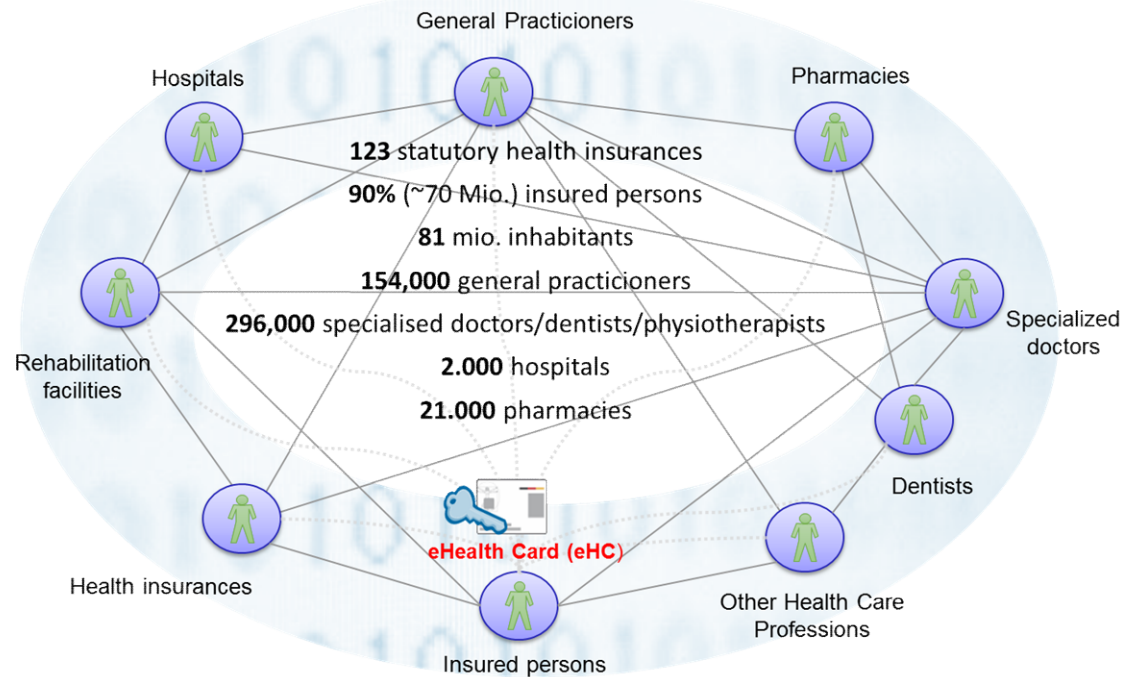


# 3

## TELEMATICS INFRASTRUCTURE

- Test roll-out:  
Q3 2016
- Federal roll-out:  
Q3 2017
- First applications:  
Q1 2018

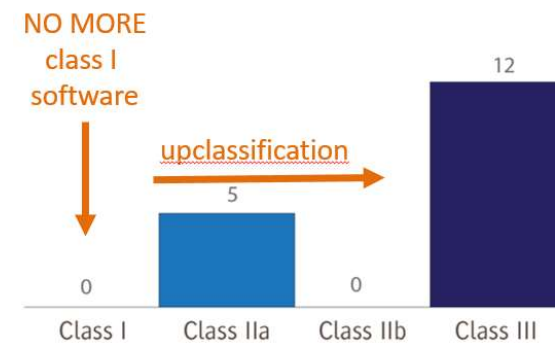
[www.gematik.de](http://www.gematik.de)



# 4

## EUROPEAN REGULATION

- ▶ General Data Protection Regulation (EU GDPR)
  - ▶ New requirements applicable in May 2018
  - ▶ Germany first EU member to adjust national law to fit the requirements of the EU GDPR (expected before fall 2017)
- ▶ Medical Device Regulation (MDR)
  - ▶ National Implementation Process initiated (bvitg an advisor to the process)
  - ▶ Art. 11 MDR!



# 5

## OUTLOOK



- ▶ Effects of Federal Health Funds for Innovations ([www.innovationsfonds.g-ba.de](http://www.innovationsfonds.g-ba.de))?
- ▶ Effects of General Data Protection Regulation on disharmony of regional data protection laws?
- ▶ eHealth Act 2.0?
  - ▶ eHealth Strategy?
  - ▶ Financing and reimbursement of digital health solutions?
  - ▶ Prevalence of Electronic Patient Records?
  - ▶ Quality assessment of medical applications?
  - ▶ Interoperability (technological and semantic)?
  - ▶ Digitalization of nursing?
  
- ▶ **Whatever the Details, Germany is finally in motion!**

## GET IN TOUCH



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