

# *GMP-Anforderungen: Rückblick, Heute und Ausblick*

Thomas Peither, Maas & Peither AG, GMP-Verlag

GMP-BERATER Tage 2019

Freiburg-Munzingen, 24. Oktober 2019

*Maas & Peither*

# *Rückblick*

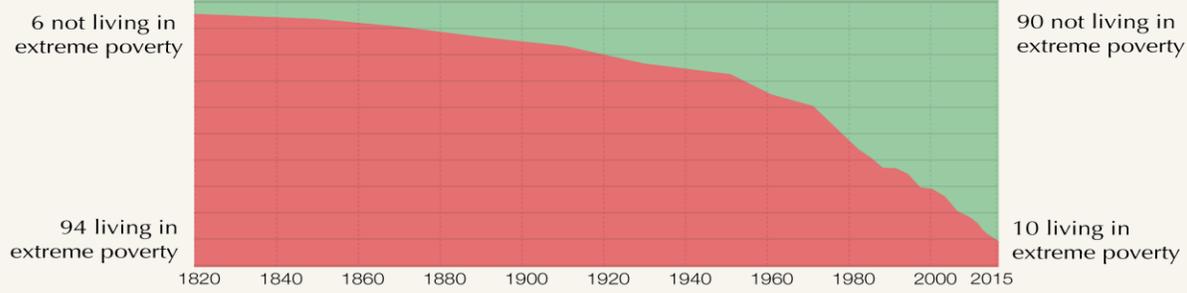
„Je weiter man zurückblickt,  
um so weiter wird man vorausschauen.“

Winston Churchill

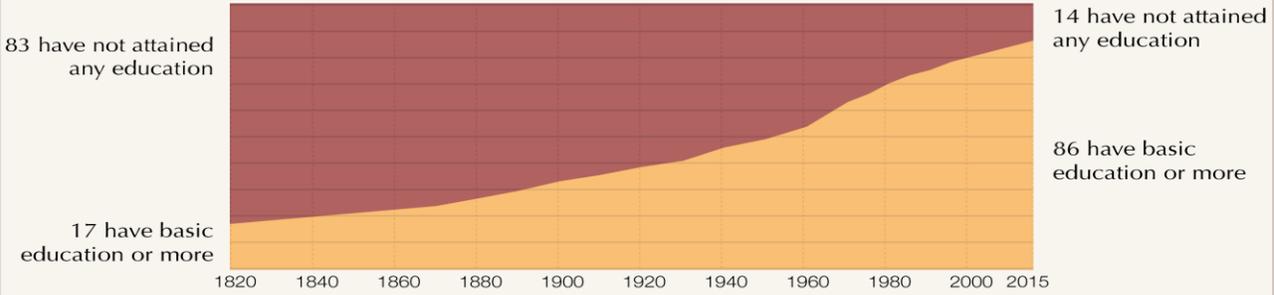
*Maas & Peither*

# The World as 100 People over the last two centuries

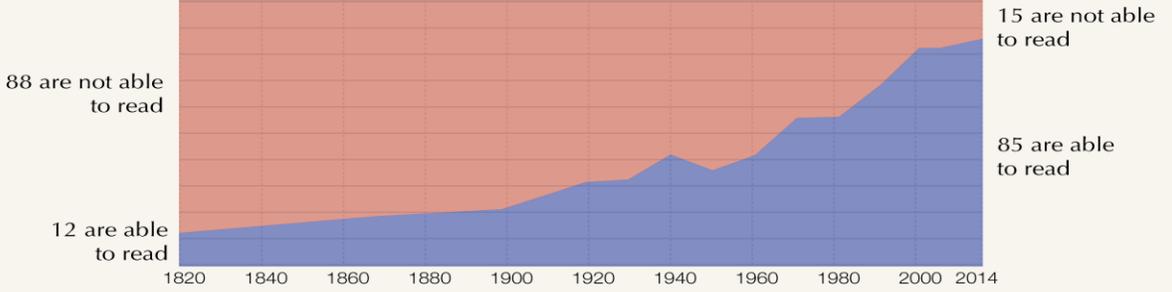
## Extreme Poverty



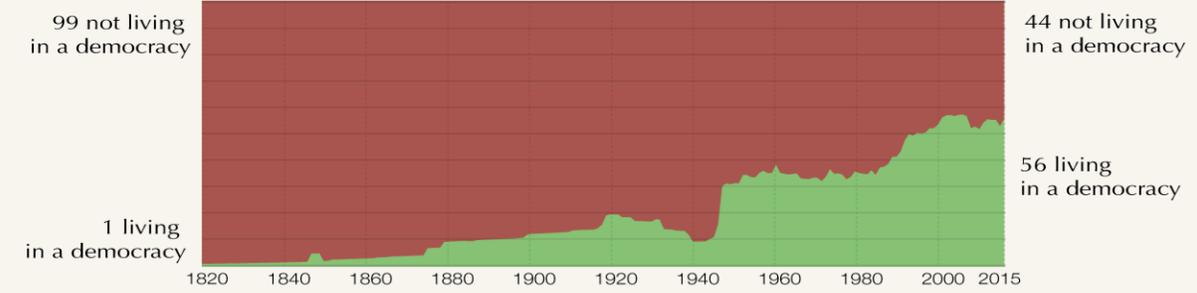
## Basic Education



## Literacy



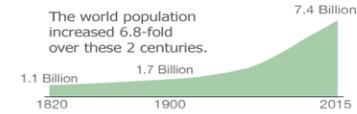
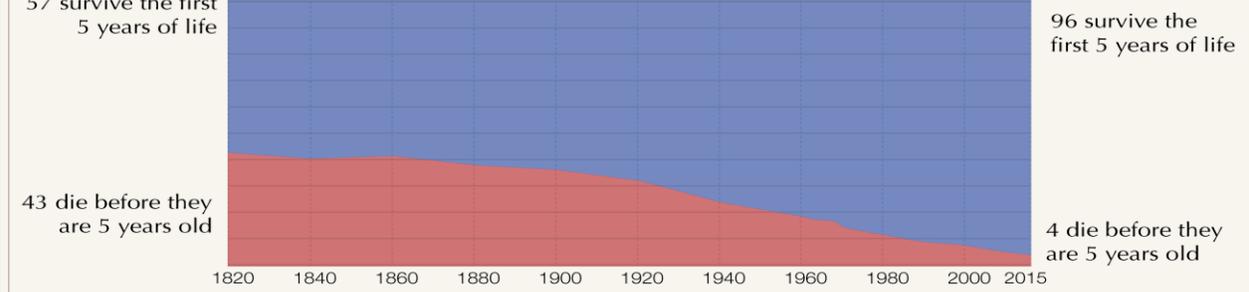
## Democracy



## Vaccination against diphtheria, pertussis (whooping cough), and tetanus



## Child Mortality



All these visualizations are from [OurWorldInData.org](http://OurWorldInData.org) an online publication that presents the empirical evidence on how the world is changing.

**Data sources:**  
 Extreme Poverty: Bourguignon & Morrison (2002) up to 1970 – World Bank 1981 and later (2015 is a projection).  
 Vaccination: WHO (Global data are available for 1980 to 2015 – the DPT3 vaccination was licenced in 1949)  
 Education: OECD for the period 1820 to 1960. IIASA for the time thereafter.  
 Literacy: OECD for the period 1820 to 1990. UNESCO for 2004 and later.

Democracy: Polity IV index (own calculation of global population share)  
 Colonialism: Wimmer and Min (own calculation of global population share)  
 Continent: HYDE database  
 Child mortality: up to 1960 own calculations based on Gapminder; World Bank thereafter

Dr. Frances  
Oldham Kelsey

10. Oktober 1962



# Eighty-seventh Congress of the United States of America

AT THE SECOND SESSION

Begin and held at the City of Washington on Wednesday, the tenth day of January, one thousand nine hundred and sixty-two

## An Act

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority; and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962".

### TABLE OF CONTENTS

#### TITLE I—DRUGS

##### PART A—AMENDMENTS TO ASSURE SAFETY, EFFECTIVENESS, AND RELIABILITY

- Sec. 101. Requirement of adequate controls in manufacture.
- Sec. 102. Effectiveness and safety of new drugs.
- Sec. 103. Records and reports as to experience on new drugs.
- Sec. 104. New drug clearance procedure.
- Sec. 105. Certification of antibiotics.
- Sec. 106. Records and reports as to experience on antibiotics.
- Sec. 107. Effective dates and application of part A.

##### PART B—STANDARDIZATION OF DRUG NAMES

- Sec. 111. Review and designation of official names.
- Sec. 112. Name to be used on drug label.
- Sec. 113. Exclusion of cosmetics.
- Sec. 114. Information to physicians.

##### PART C—AMENDMENTS AS TO ADVERTISING

- Sec. 131. Prescription drug advertisements.

#### TITLE II—FACTORY INSPECTION AND EFFECT ON STATE LAWS

- Sec. 201. Factory inspection.
- Sec. 202. Effect on State laws.
- Sec. 203. Effective date.

#### TITLE III—REGISTRATION OF DRUG ESTABLISHMENTS AND PATENT INFORMATION

- Sec. 301. Findings and declaration.
- Sec. 302. Registration of producers of drugs.
- Sec. 303. Transitional provisions.
- Sec. 304. Failure to register.
- Sec. 305. Drugs from nonregistered establishments misbranded.
- Sec. 306. Samples of imported drugs.
- Sec. 307. Definitions.
- Sec. 308. Information on patents for drugs.

#### TITLE I—DRUGS

##### PART A—AMENDMENTS TO ASSURE SAFETY, EFFECTIVENESS, AND RELIABILITY

###### REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

Sec. 101. Clause (2) of section 501(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)) is amended to read as follows: "(2) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not

### SAMPLES OF IMPORTED DRUGS

SEC. 306. Section 801(a) of such Act (21 U.S.C. 381(a)) is amended by inserting, after the first sentence thereof, the following new sentence: "The Secretary of Health, Education, and Welfare shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs be delivered to the Secretary of Health, Education, and Welfare, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony."

### DEFINITIONS

SEC. 307. (a) Section 201(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)) is amended to read as follows:

"(1) The term 'State', except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

"(2) The term 'Territory' means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone."

(b) The second sentence of section 702(a) of such Act (21 U.S.C. 372(a)) is amended by inserting before the words "a Territory" the words "the Commonwealth of Puerto Rico or".

### INFORMATION ON PATENTS FOR DRUGS

SEC. 308. Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by adding at the end thereof the following new subsection:

"(d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required."

Speaker of the House of Representatives.

Carl Hayden

Vice President of the United States and President of the Senate pro tempore

Approved -  
October 10<sup>th</sup> 1962  
White House -  
Washington - P.C.  
John Edgar Hoover Kennedy



# *Kefauver-Harris-Amendment 1962 FD&C Act*

[...] if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with **current good manufacturing practice** to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; [...]

*Maas & Peither*

# Entwicklung der Good Manufacturing Practice in Europa und Deutschland

1961: Als letztes Land der EWG gründet die BRD das Bundesgesundheitsministerium  
1. Arzneimittelgesetz mit Registrierungspflicht ohne Prüfung oder klinische Prüfung

1971: Richtlinie über die Prüfung von Arzneimitteln – Etablierung der Grundsätze für die pharmakologisch-toxikologische und klinische Prüfung von Arzneimitteln



**EG-GMP Leitfaden Neufassung AMWHV (D)**  
Arzneimittel- und Wirkstoffherstellungsverordnung

**Gründung Europäische Arzneimittelagentur**  
zunächst als EMEA, später EMA

**EG-GMP Leitfaden**  
Nach 2009 EU-GMP Leitfaden

**Pharmabetriebsverordnung (D)**

**2. Arzneimittelgesetz (D)**

Richtlinie des Rates zur Angleichung der Rechts- und Verwaltungsvorschriften über Arzneispezialitäten

**EWG Richtlinie 65/65/EWG**

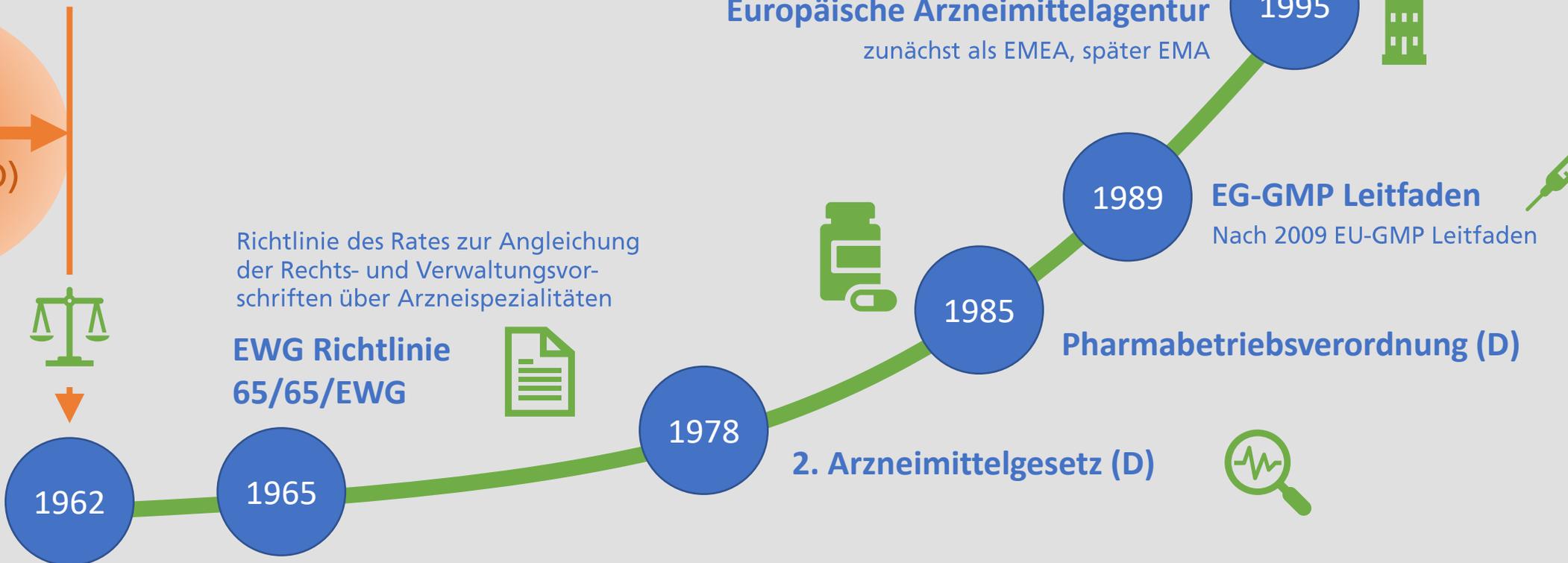


Thalidomid  
rezeptfrei (D)  
1957-1962



**USA: FD&C Act Amendment**

Food, Drug & Cosmetic Act von 1938

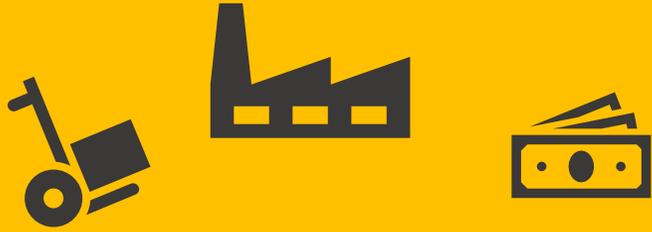


# *Heute*

„Wer vor der Vergangenheit die Augen verschließt,  
wird blind für die Gegenwart.“

Richard von Weizäcker

*Maas & Peither*



Globale Handels- und Produktionsketten, Zölle

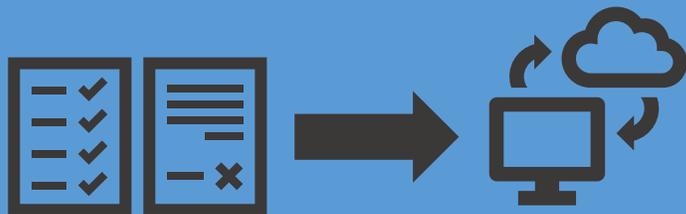
Vernetzung von Geschäftsprozessen



Automatisierung in Herstellung, Instandhaltung, Logistik

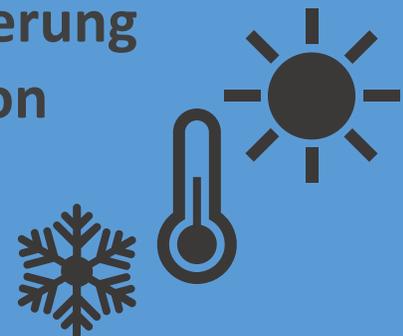
## Aktuelle Themen für Pharmazeutische Betriebe und deren Qualitätssicherung

Digitalisierung analoger Prozesse



Steigerung der Nachhaltigkeit

Auswirkung der Klimaveränderung auf Produktion Krankheiten Menschen

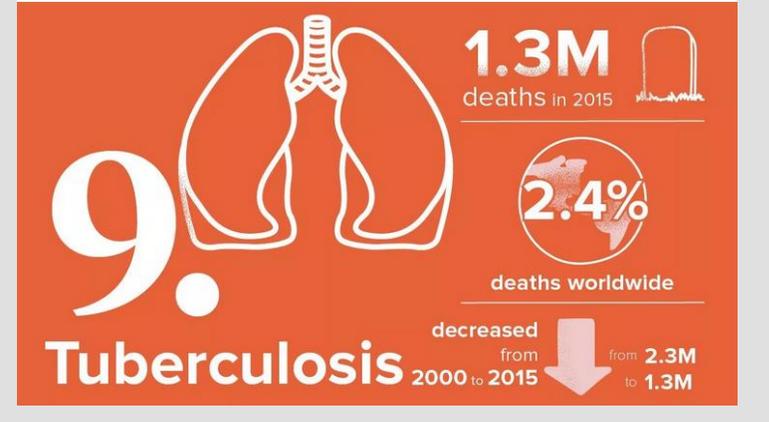
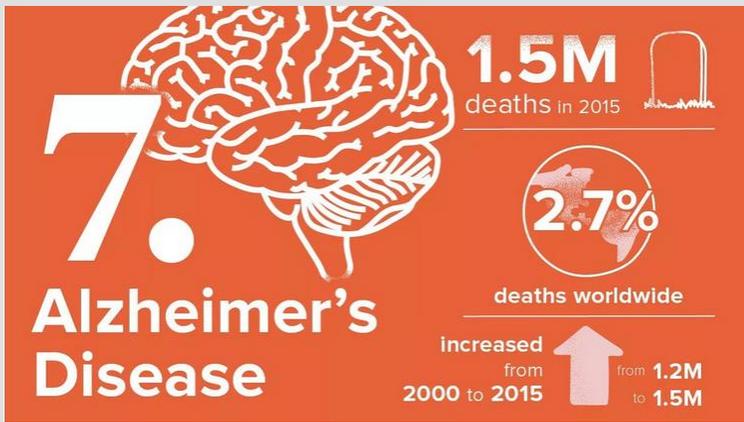
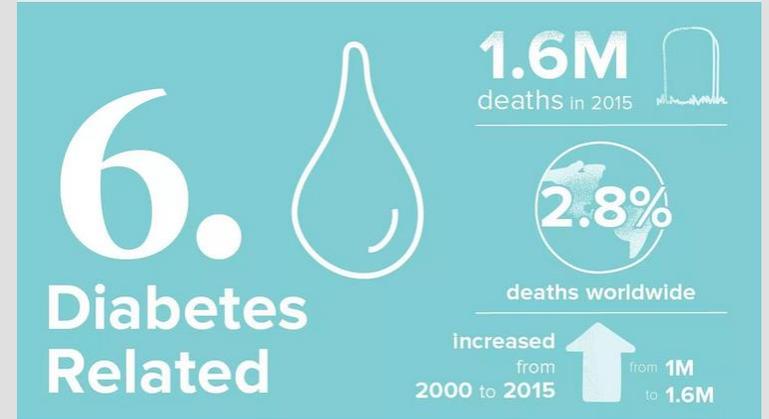
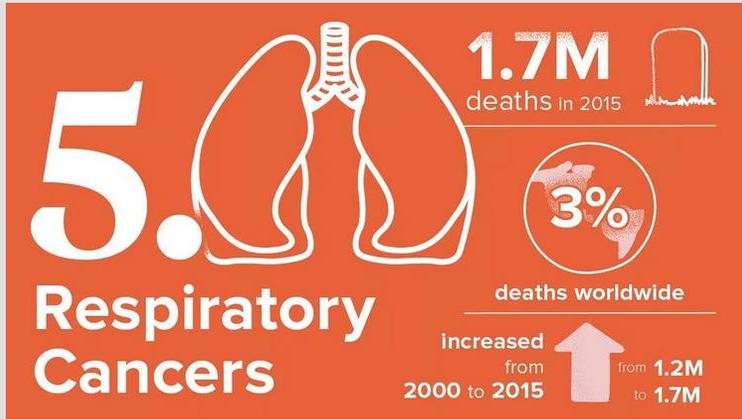
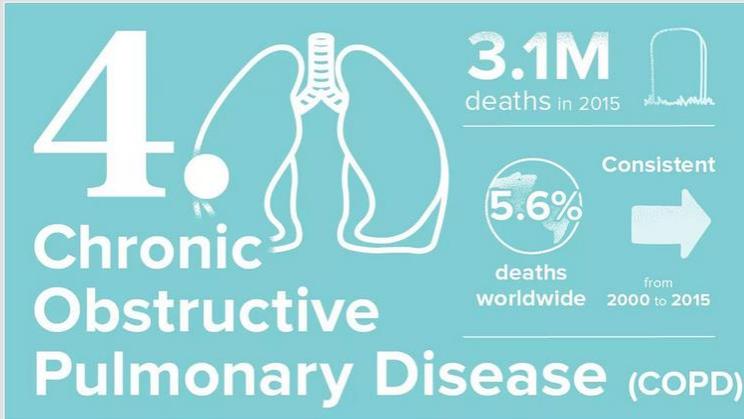
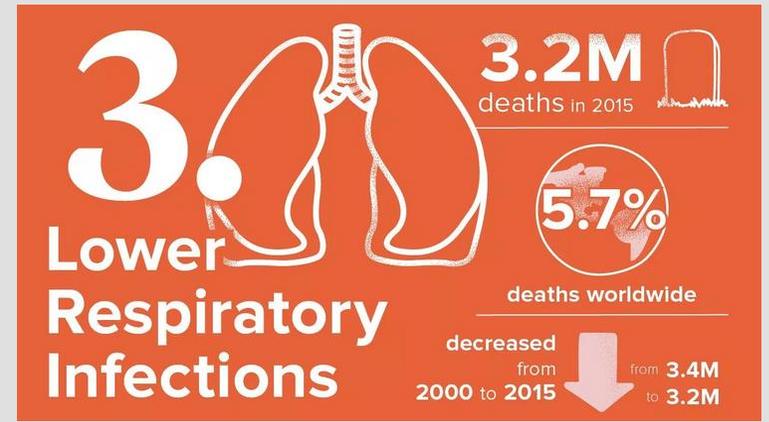
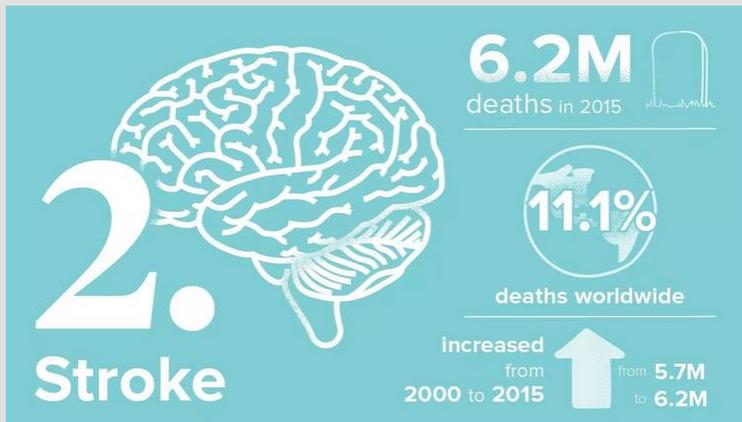
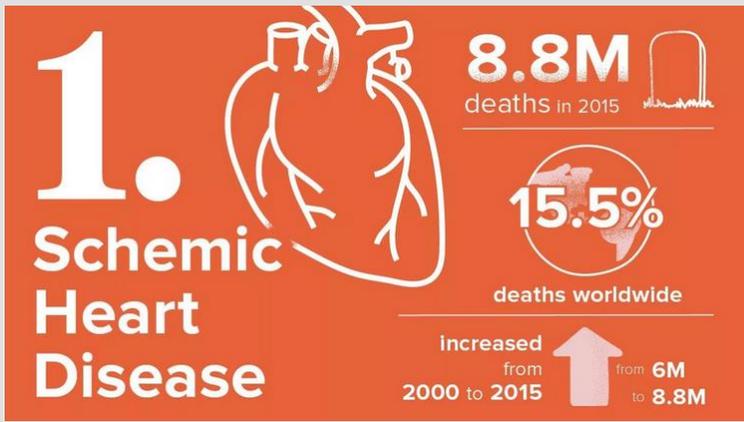


# *Datenintegrität ist essentiell!*

Computer betrachten Kommunikation nicht als eine Kette von Missverständnissen, sondern als präzisen sachlichen Informationsaustausch.

Damit sind sie in diesem Punkt vielen Formen der menschlichen Kommunikation überlegen.

*Maas & Peither*



**Settings** Use basic settings

**Display** Cause Risk  
Etiology Impairment  
Injuries by nature

**Measure** Deaths ▾

**Location** Central Europe ▾

**Year** 2017

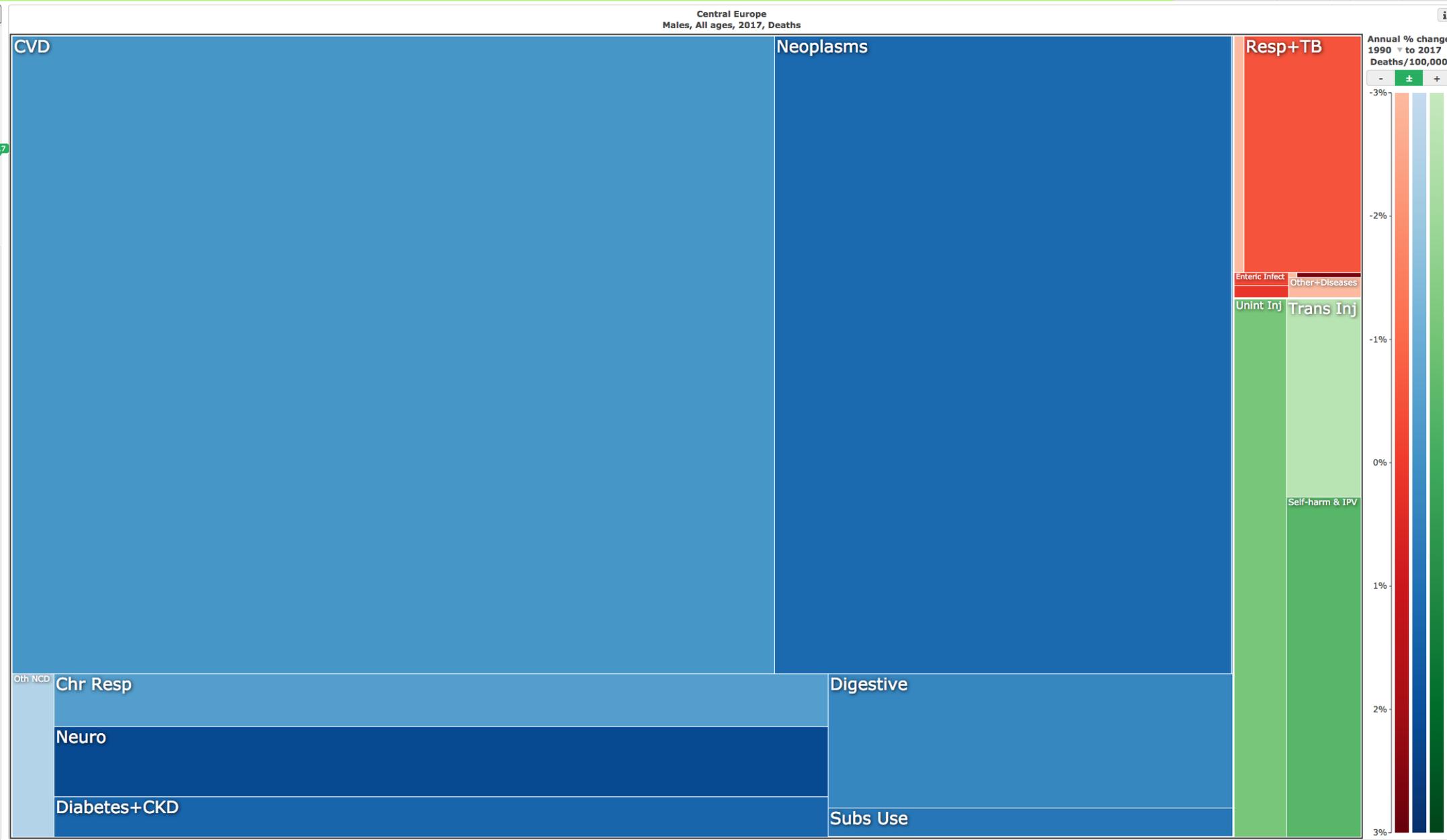
**Age** All ages ▾

**Sex** Male Female Both

**Level** 2

**Value** Observed Expected

[Take tour ▶](#)



# *Ausblick*

„Mehr als die Vergangenheit interessiert mich die Zukunft, denn in ihr gedenke ich zu leben.“

Albert Einstein

*Maas & Peither*

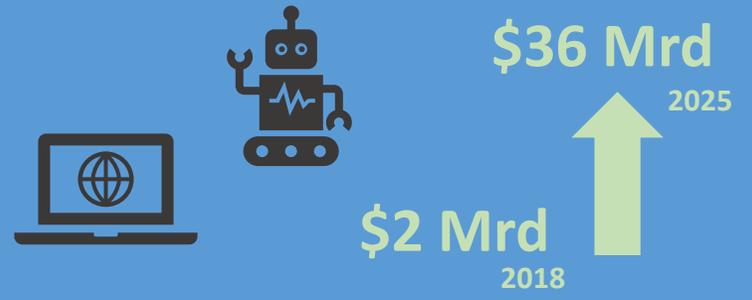


**Bioökonomie**  
**Personalisierte Medizin**

### Pflanzenbasierte Medizin & Ernährung



*Menschen in den USA werden zwar älter als in China, verbringen jedoch auch einen größeren Anteil ihres Lebens mit Krankheiten.*



**Künstliche Intelligenz**  
**Machine Learning**



**Diese Themen werden uns  
in Zukunft beschäftigen!**



### Internet der Dinge (IoT)

**\$534 Mrd**  
2025

**\$120 Mrd**  
2018



**\$150 Mrd**  
2025

**\$4 Mrd**  
2015

**Mobiles  
Gesundheitssystem**

### Blockchain Sicheres Dokumentieren



# Viel Vergnügen bei den GMP-BERATER Tagen 2019



# Quellen

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*Maas & Peither*