Swissmedic Regulatory News - Bereich Zulassung 11.12.2017

# Zulassung 2017

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Claus Bolte, Leiter Bereich Zulassung

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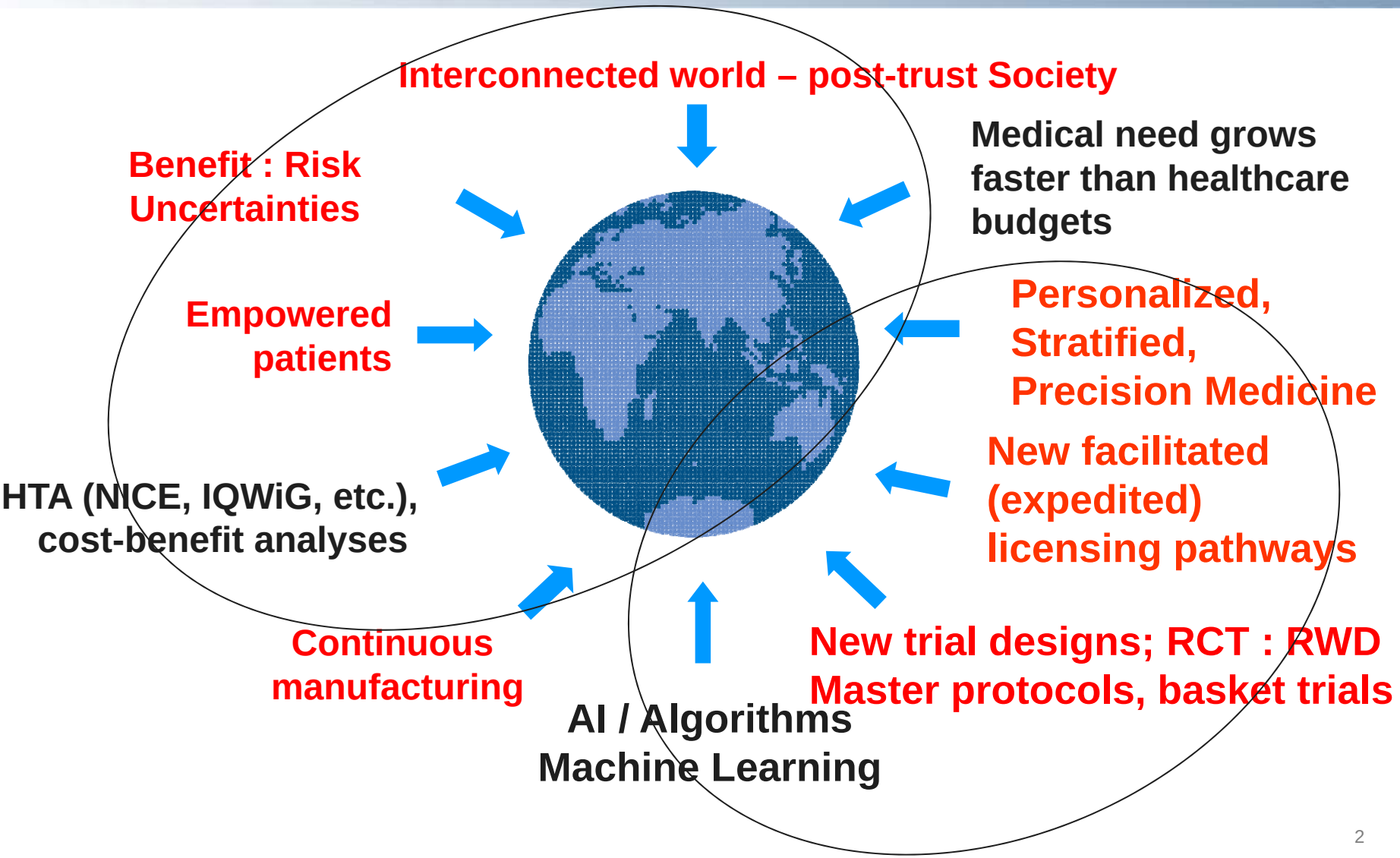
# Context



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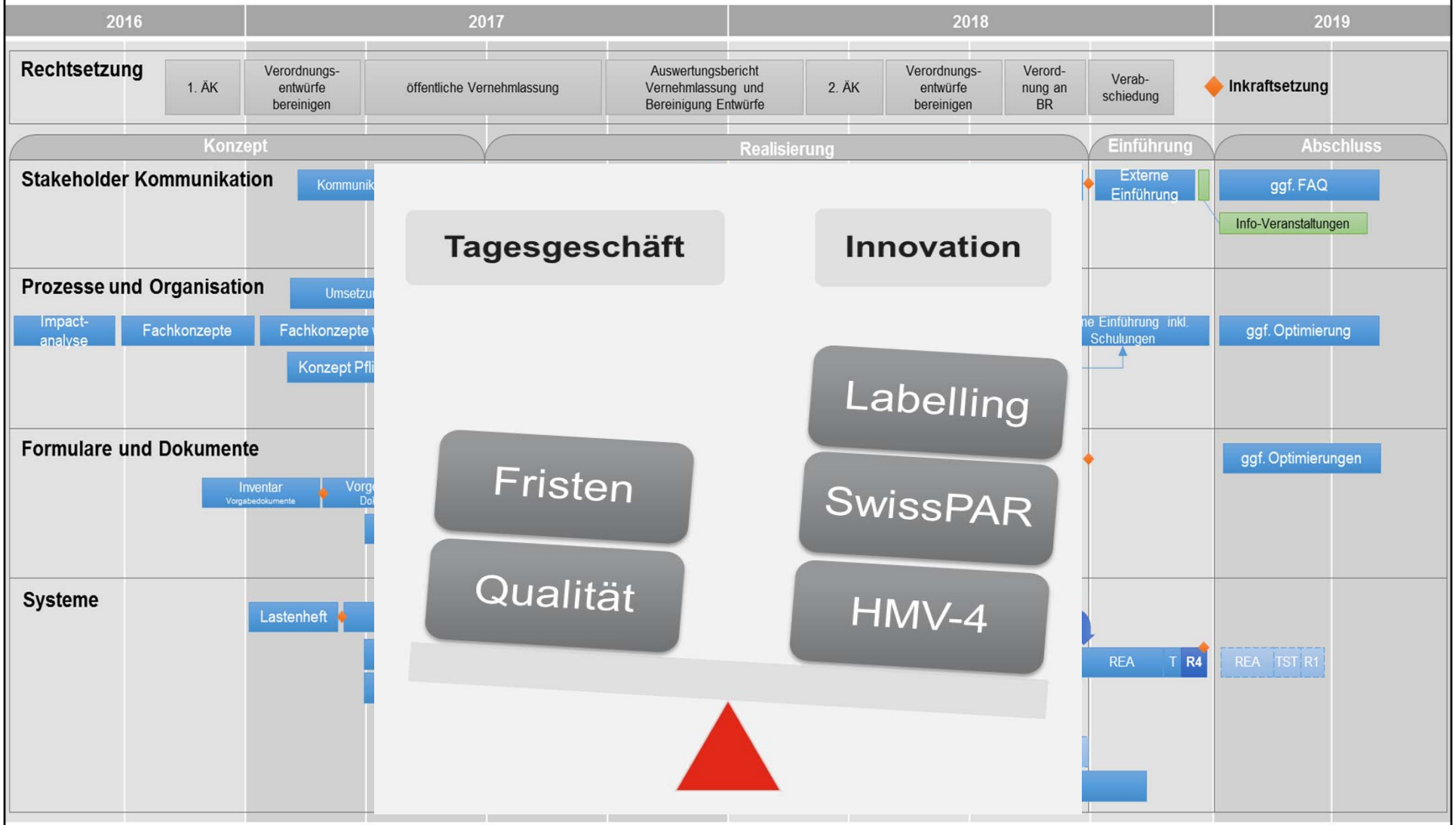
# HMV-4



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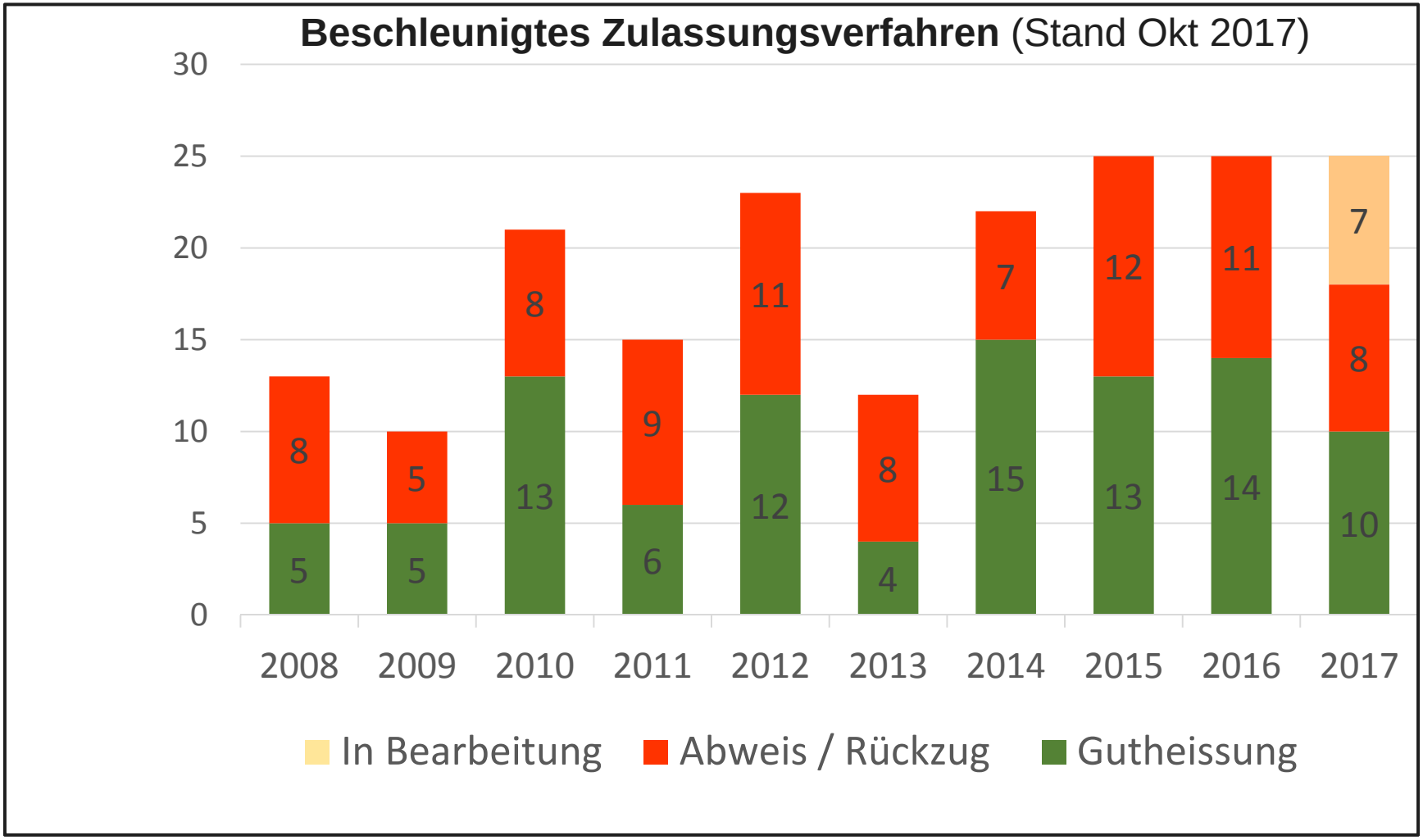
# BZV Anträge



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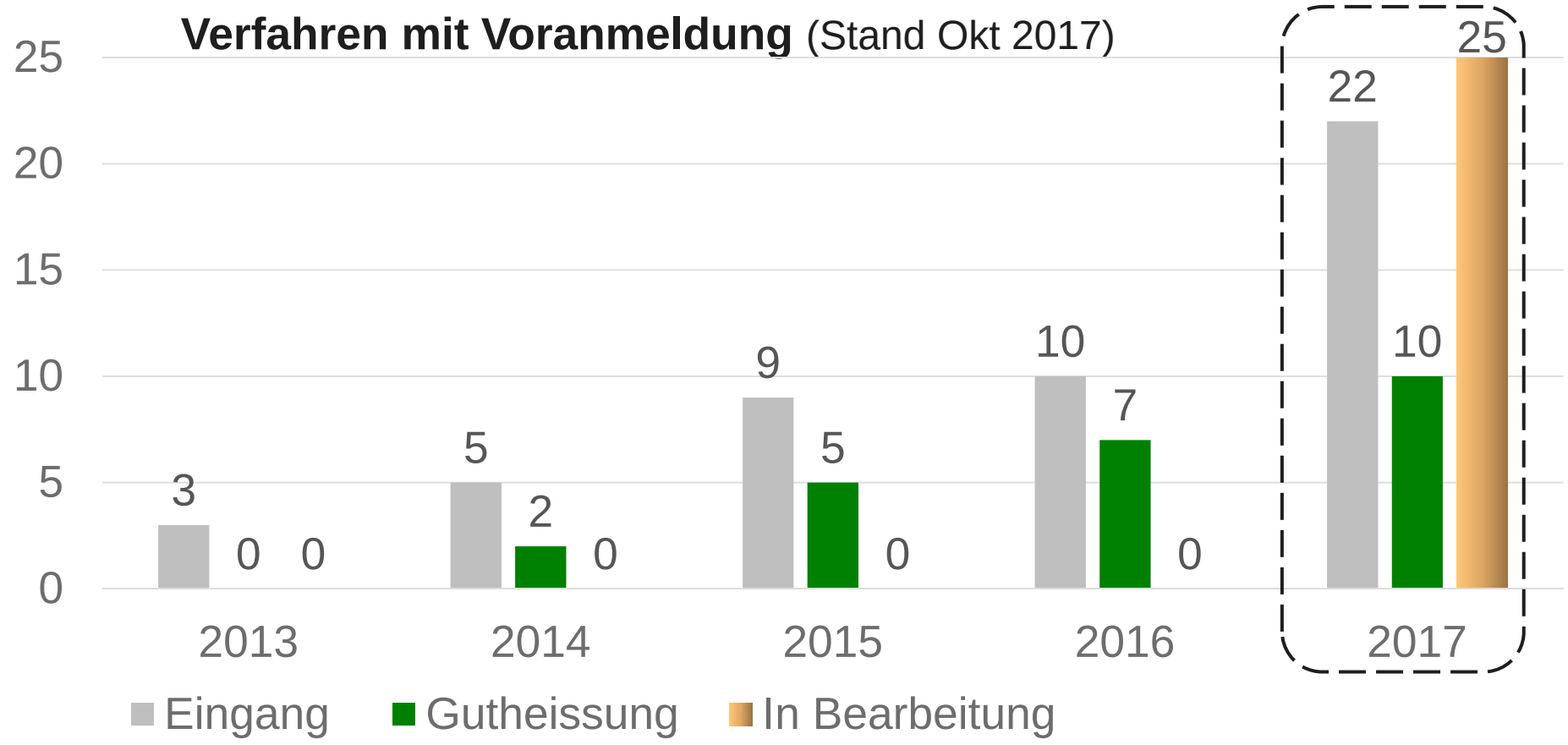
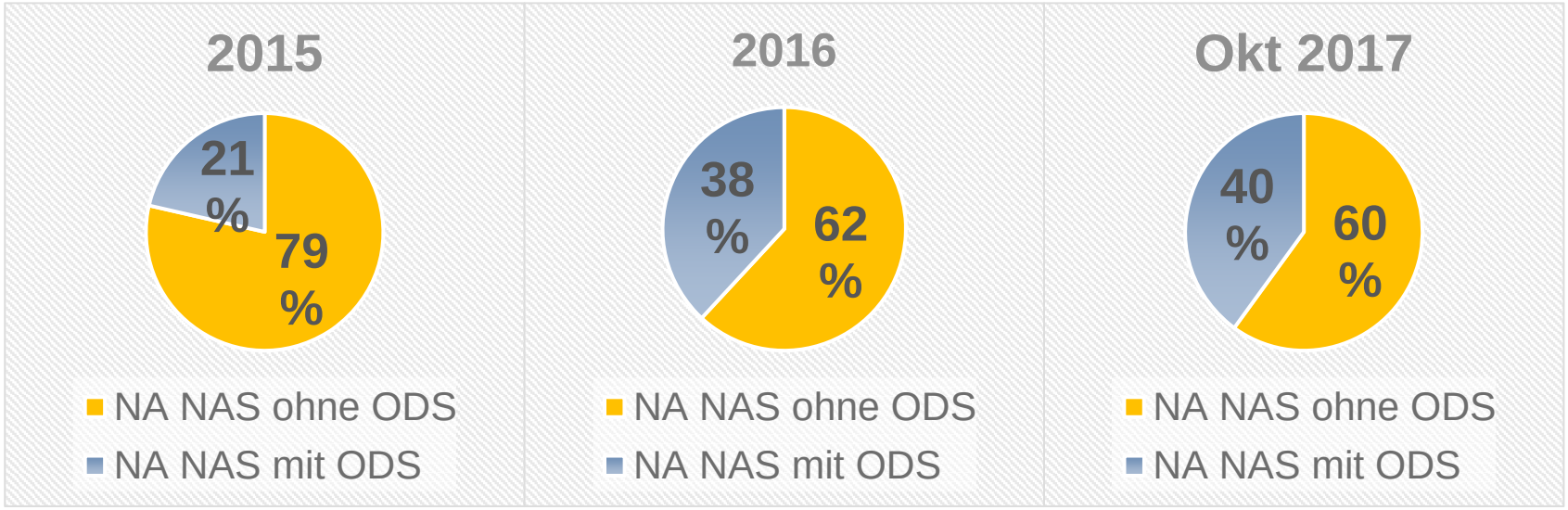
# VmVA




- 2017 wurden 22 Zulassungsgesuche im VmVA eingereicht und 10 gutgeheissen
- 25 Gesuche sind in Bearbeitung bzw. zur Einreichung im 2017 angemeldet.
- Die Gesuche wurden zu **100%** fristgerecht abgeschlossen.

# Gutgeheissene NA NAS mit Orphan Drug Status




| Gesuchstyp / Verfahren | 2014 | 2015 | 2016 | Okt 2017 |
|---|---|---|---|---|
| NA NAS | 37 | 28 | 42 | 30 |
| NA NAS mit ODS | 10 (27%) | 6 (21%) | 16 (38%) | 12 (40%) |
| NA NAS mit ODS im BZV | 3 | 3 | 2 | 4 |
| Antrag Status ODS<br>→ Status gewährt | 20<br>20 (100%) | 34<br>28 (82%) | 40<br>39 (98%) | 43<br>42 (98%) |

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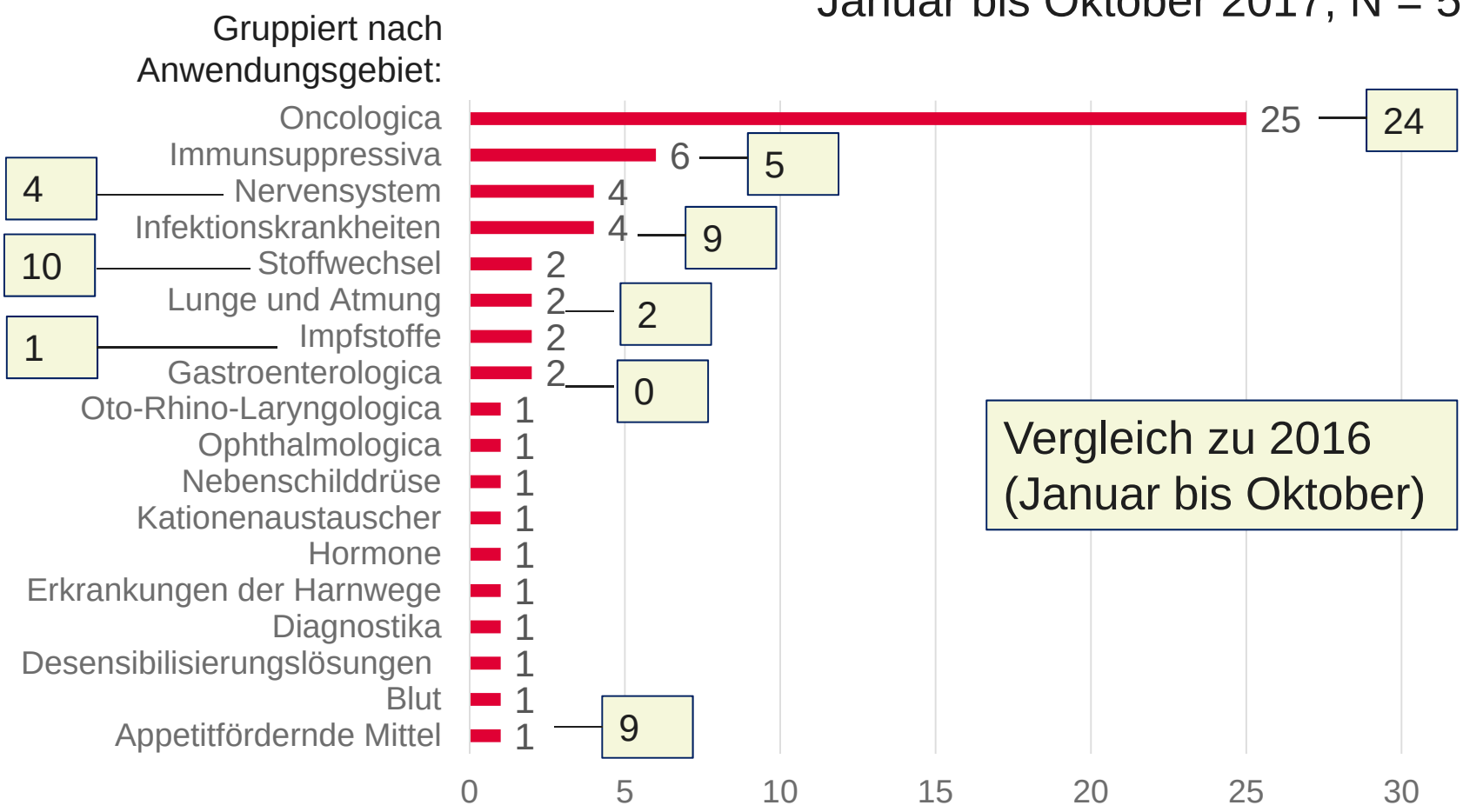
SMEC

# HMEC-Empfehlungen

Januar bis Oktober 2017, N = 57



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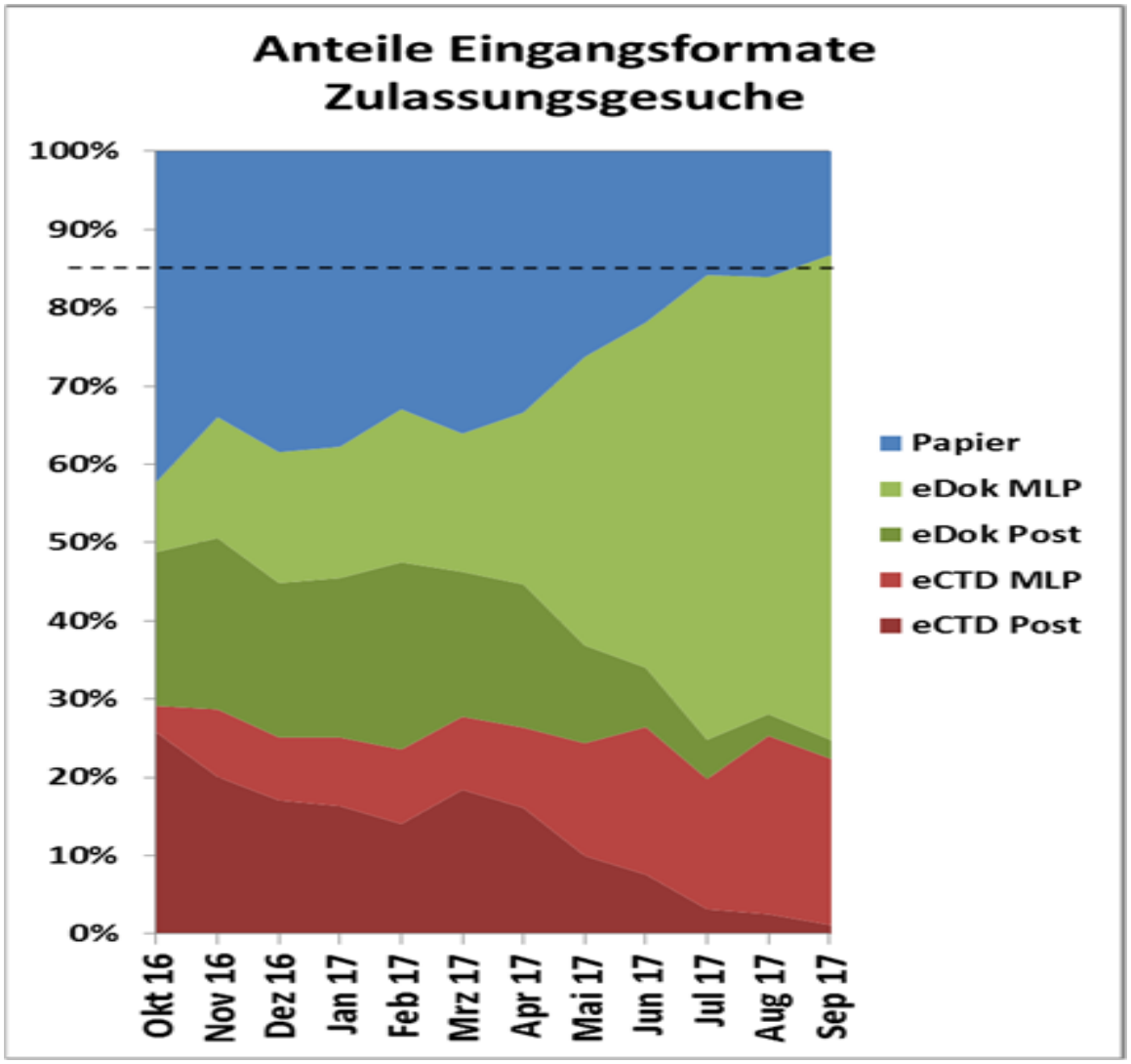
# eGov




eSubmissions-Plattform

Der Anteil der reinen Papiereinreichungen (blau) ist im September erstmals auf unter **15%** gesunken.

Innerhalb der eDok und eCTD Formate ist der den Anteil der per MLP eingereichten Gesuche am hellerem Farbton.

eCTD und eDok werden **fast ausschliesslich** per Plattform (MLP) eingereicht.

# Gesamtdauer Labelling-Phase

NA NAS: Für ca. **8 %** des Aufwandes wird ca. **ein Drittel** der Zeit benötigt.

| Gesuchstyp | Labelling-Dauer [KT] | % Labelling an Gesamtzeit |
|---|---|---|
| Neue aktive Substanz | 157 | 32% |
| Bekannte Wirkstoffe mit Innovation | 203 | 38% |
| Bekannte Wirkstoffe ohne Innovation | 150 | 34% |
| Indikationserweiterungen | 128 | 31% |
| Neue Dosierungsempfehlungen, -stärken, galenische Formen | 129 | 34% |
| Alle Gesuche | 144 | 34% |

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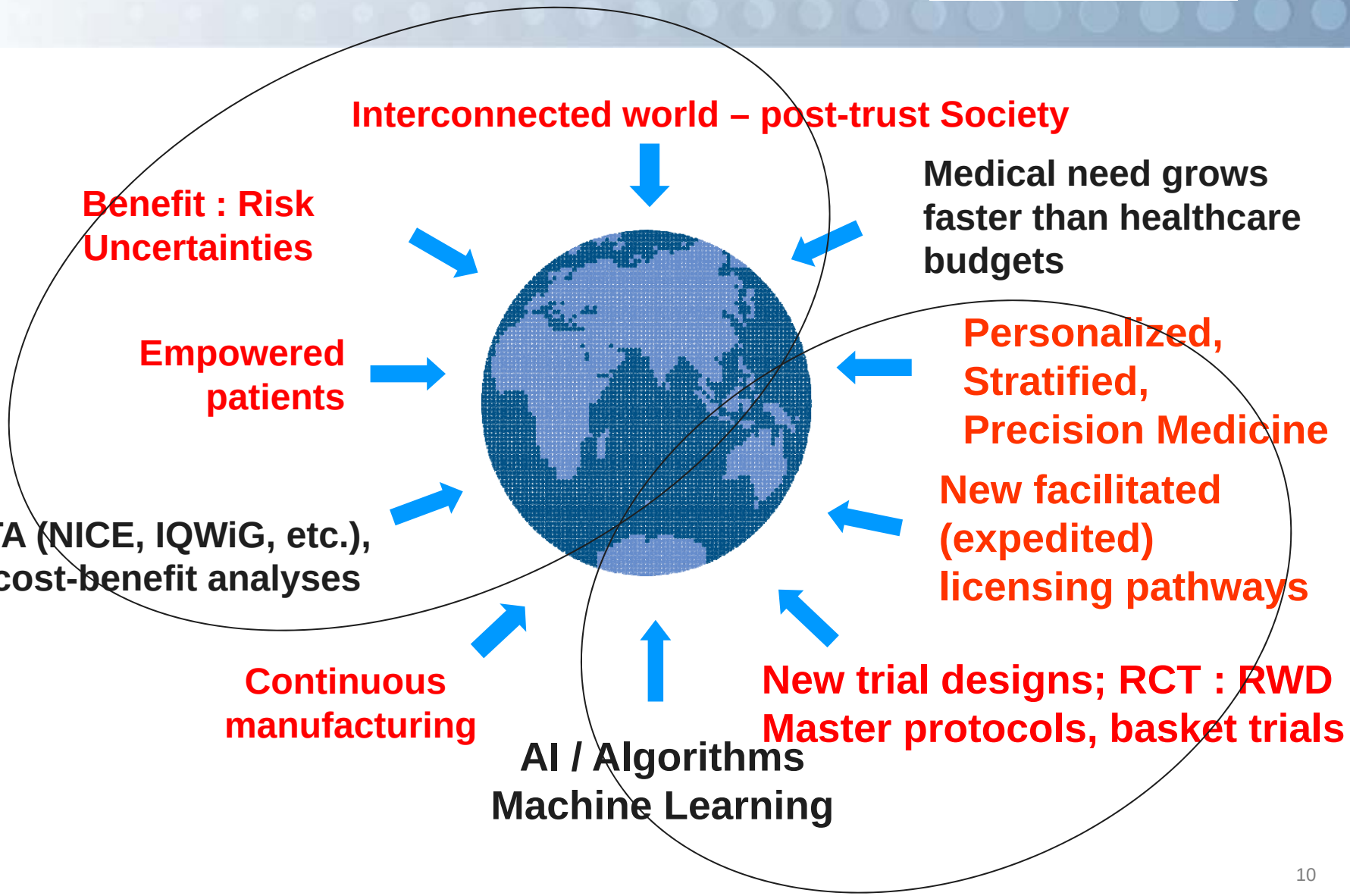
# Context



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# (post-)Trust?

Established in 1871
SMW
Swiss Medical Weekly
Formerly: Schweizerische Medizinische Wochenschrift
The European Journal of Medical Sciences

Review article: Current opinion | Published 13 March 2015, doi:10.4414/smw.2015.14120
Cite this as: Swiss Med Wkly. 2015;145:w14120

## Only conflicts of interest?

*Reto Obrist*

Former director / chief physician, Cantonal Oncology Department, Valais, Switzerland

cation. In the words of Nassim Taleb: "The relation of a career scientist to science corresponds to the relation of a prostitute to love" [22].

**Summary**

The current situation of the biomedical sciences is critically discussed. It can be summarized as follows:
1. We have to acknowledge the presence of a serious credibility problem, which might undermine the foundations of medical science. ("Sliding on a slippery slope")
2. Multiple forces going beyond simple conflicts of interest push medical science further down the slippery slope. ("Who is pushing?")
3. The public awareness of something seriously wrong with medical science is mounting on all levels of our multimedia society. ("Looking into the media mirror")
4. Technical corrective measures may be easily implemented, however, to change an expanding and "successful" science culture actually destroying it's own foundations will need a sustained effort by the medical and scientific community on all levels. ("Look away - or act?")

***Key words:*** *biomedical science; irreproducibility; publication bias; ethical blindness; scientific integrity*

Examples of potential COIs in medical research are:
- Patient care vs doctor / clinical researcher as agent for research;
- Scientific truth vs career opportunities (publication numbers, impact factors, university rankings);
- Science vs marketing (pharma, doctors, publishers);
- Healthcare system costs vs income/expenses of doctors, hospitals, cantons, pharma, insurance).

The common denominator is that a third party is at risk,

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# Transparenz - pEB

| Gesuchstyp | Anzahl Gesuche |
|---|---|
| NA NAS HAM | 11 |
| NA BWS mit Innovation | 55 |
| NA BWS ohne Innovation | 41 |
| NA BWS HAM-KPA | 2 |
| NA BWS NKO HAM | 3 |
| NA AM Art. 12 Abs. 4 VAZV | 20 |
| NA Biosimilar | 0 |
| W-AE IE | 30 |
| W-AE NDE | 8 |
| W-AE NDO | 5 |
| W-AE NGF | 7 |
| **Total** | **132 (=100%)** |

Versand parteiöffentlicher EB für Verfügungen im 1. Halbjahr 2017

<u>Fragen > Antworten</u>

- sinnvoll?
- Nutzen : Aufwand?
- Feedback?

# Public Meeting on Benefit-Risk Framework Implementation

September 18, 2017

**Session 3 – Special Topics in Benefit-Risk Assessment**

| | |
|---|---|
| 3:15 – 3:30 pm | **Advancing Decision Science Methods for Regulatory Use**<br>Baruch Fischhoff, Ph.D.,<br>Carnegie Mellon University |
| 3:30 – 3:45 pm | **Potential Areas for Quantitative Benefit-Risk Approaches**<br>Richard Forshee, Ph.D.<br>OBE, CBER, FDA |
| 3:45 – 4:00 pm | **Communicating Benefit-Risk to the Public**<br>Lisa Schwartz, M.S., M.D., & Steve Woloshin, M.S., M.D.<br>Dartmouth Institute for Health Policy and Clinical Practice and Dartmouth Medical School |
| 4:00 – 4:30 pm | **Panel Discussion and Q&A**<br><br>Panel includes Session 3 Presenters plus<br><br>Peter Stein, MD,<br>OND, CDER, FDA<br><br>Bennett Levitan, M.D. Ph.D.<br>Janssen R&D Pharmaceutical Companies of Johnson & Johnson<br><br>Clause Bolte, M.D.<br>Swissmedic |

## REVISION OF M4E GUIDELINE ON ENHANCING THE FORMAT AND STRUCTURE OF BENEFIT-RISK INFORMATION IN ICH

## EFFICACY - M4E(R2)

*2.5.6.4 Benefit-Risk Assessment*

When **describing** the benefit-risk assessment, the following additional aspects should be considered:

- The impact of the therapeutic context on the assessment, which may include information on the patient perspective if available. This discussion should consist of the following:
  - how the severity of disease and expected benefit influence the acceptability of the risks of the therapy.
  - how the medicinal product addresses a medical need.
- Key aspects of risk management that are important in reaching a favourable benefit-risk assessment, such as:
  - the proposed labeling.
  - whether non-responders can be readily identified allowing them to discontinue treatment.
  - other risk management activities, such as registries or restricted distribution systems.

There are many approaches available for conducting the benefit-risk assessment. This guideline does not prescribe a specific approach. A descriptive approach that explicitly communicates the interpretation of the data and the benefit-risk assessment will generally be adequate. An applicant may choose to use methods that quantitatively express the underlying judgments and uncertainties in the assessment. Analyses that compare and/or weigh benefits and risks using the submitted evidence may be presented. However, before using any method,

2017 ASCO ANNUAL MEETING

Making a Difference in Cancer Care *WITH YOU*

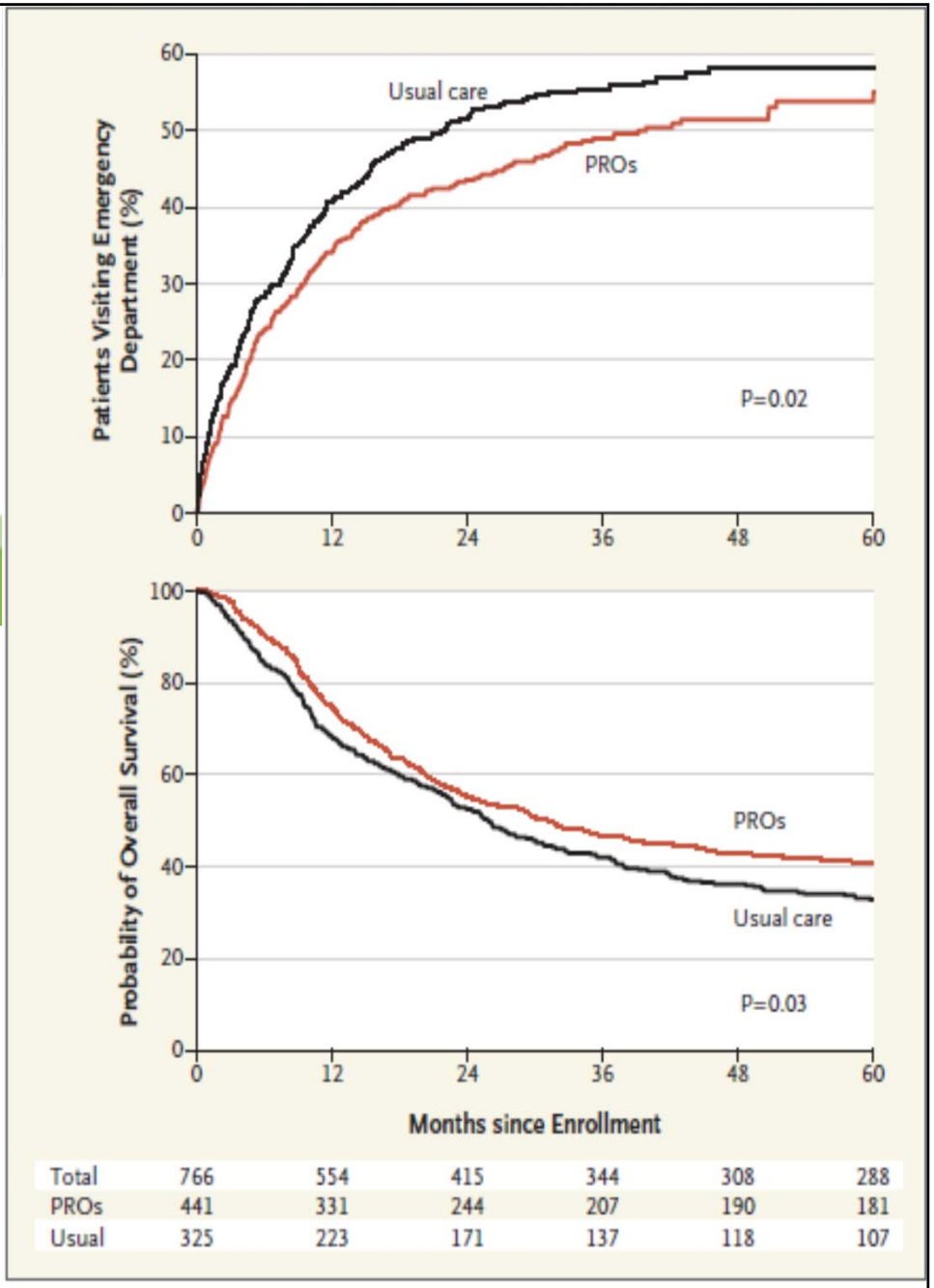
1:00 PM - 4:00 PM Plenary Session

Plenary Session Including the Science of Oncology Award and Lecture

Location: Hall B1 (Simulcast Location: Hall D1)

**Overall survival results of a randomized trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment.**

(**Abstract LBA2**) *E. M. Basch*, A. M. Deal, A. C. Dueck, A. V. Bennett, T. M. Atkinson, H. I. Scher, M. G. Kris, C. A. Hudis, P. Sabbatini, D. Dulko, L. J. Rogak, A. E. Barz, D. Schrag




| | | | | | | |
|---|---|---|---|---|---|---|
| Total | 766 | 554 | 415 | 344 | 308 | 288 |
| PROs | 441 | 331 | 244 | 207 | 190 | 181 |
| Usual | 325 | 223 | 171 | 137 | 118 | 107 |

**Emergency Department Visits and Probability of Survival Associated with Integrating Patient-Reported Outcomes (PROs) into Cancer Care.**

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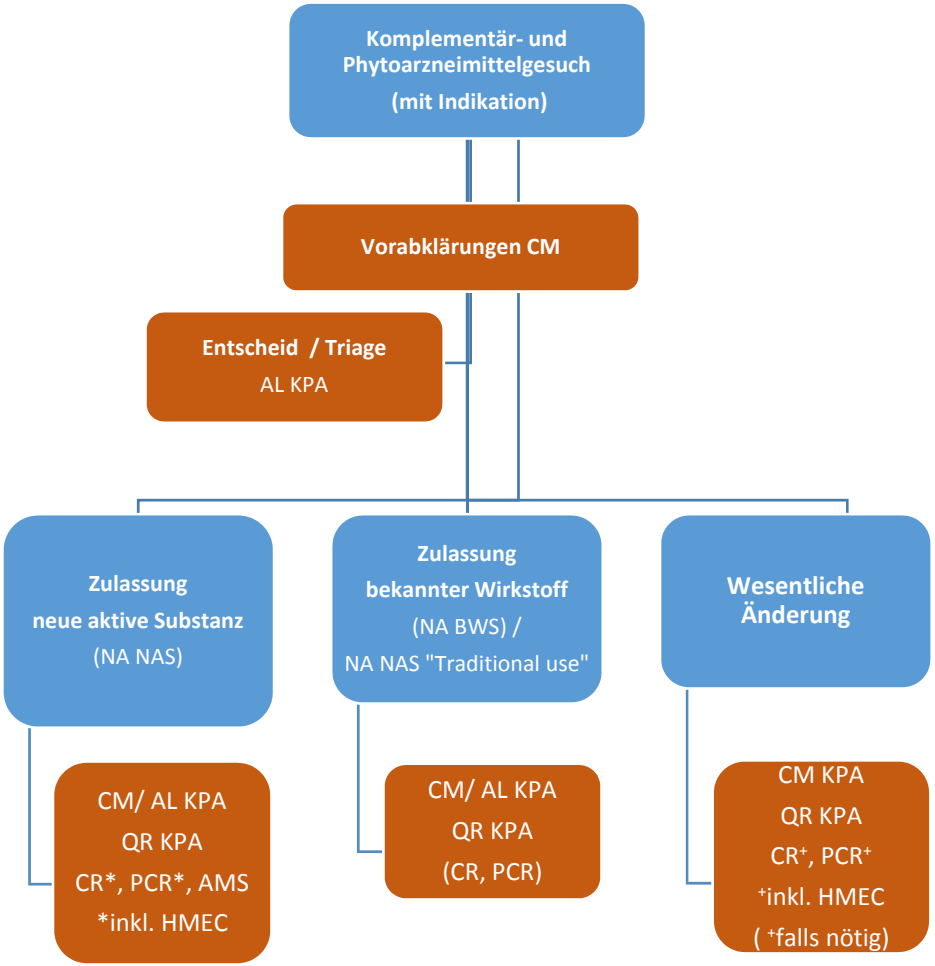
# KPA




# Interactions between traditional Chinese medicines and Western therapeutics.

Curr Opin Drug Discov Devel. 2010 Jan;13(1):50-65.

**Interactions between traditional Chinese medicines and Western therapeutics.**

Chan E1, Tan M, Xin J, Sudarsanam S, Johnson DE.
Emiliem Inc, Emeryville, CA 94608, USA.

**Abstract**

Traditional Chinese medicine (TCM) is a holistic approach to health that attempts to bring the body, mind and spirit into harmony. … **An integration of the traditional Chinese and Western systems of medicine has begun in multiple medical centers internationally**, and there is increasing evidence that several herbs and combinations of herbs used in TCM impart important pharmacological effects. … when TCM is used in combination with other drugs. **Herb-drug interactions are similar to drug-drug interactions in terms of their effects on ADME properties**. Improvements in the knowledge of the molecular targets and metabolic pathways … will lead to the development of rational approaches for the safe combination of healthcare systems from different cultures.

Eingefügt aus
<https://www.ncbi.nlm.nih.gov/pubmed/20047146?report=abstract>

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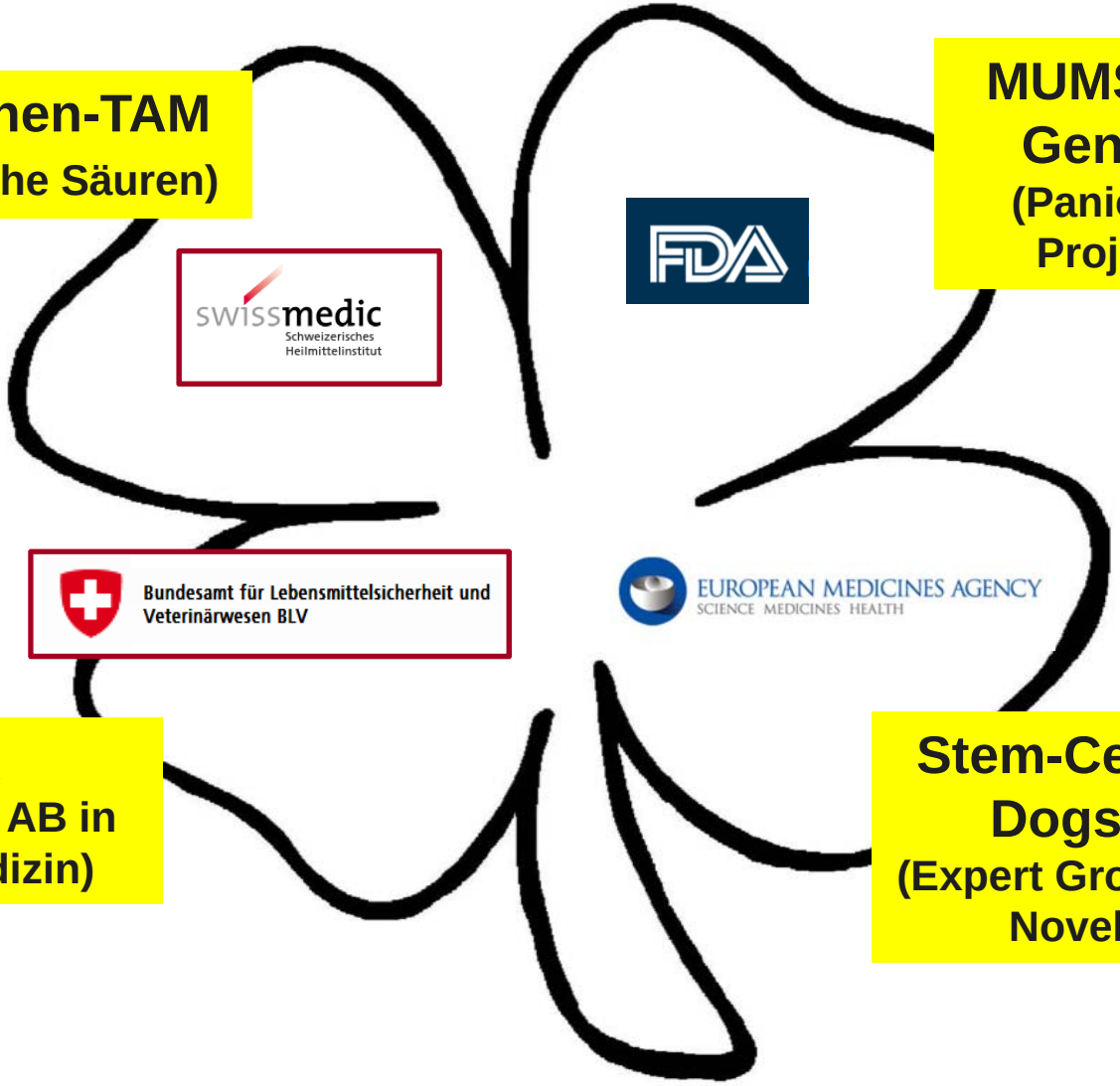
# TAM

**«Öko»-Bienen-TAM**
**(z.B. organische Säuren)**




**MUMS-Status for Gene-Therapy**
**(Panion's Epilepsy Project in Dogs)**

**STAR**
**(Einsatz von AB in der Tiermedizin)**

**Stem-Cell Therapy in Dogs & Horses**
**(Expert Group on Veterinary Novel Therapies)**

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Bundeskanzlei BK

# Vereinbarung zum Beitrag für das Buchprojekt «Die Schweiz im Jahr 2030»

?

- (post-)Trust
- ZL Verfahren
- Datenquellen
- Evaluation - B:R:U
- Value