

# Labordaten

## Gefahren bei der Auswertung

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Uniklinik Köln

12/2018

# Was können wir mit Labordaten anfangen?

- Diagnosen stellen und überprüfen
- Diagnostische Wertigkeit ermitteln
  - z.B. Korrelation mit Aufnahmediagnosen/ Entlassdiagnosen
- Abschätzung von biologischer Varianz
- Indirekte Ermittlung von Referenzwerten
- Abschätzung des Krankheitsverlaufs/ Prognostik
- Ermittlung von Prävalenzen /
  - z.B. Abschätzung des Screeningaufwands bei klinischen Studien

„Neue“  
Anwendungen?

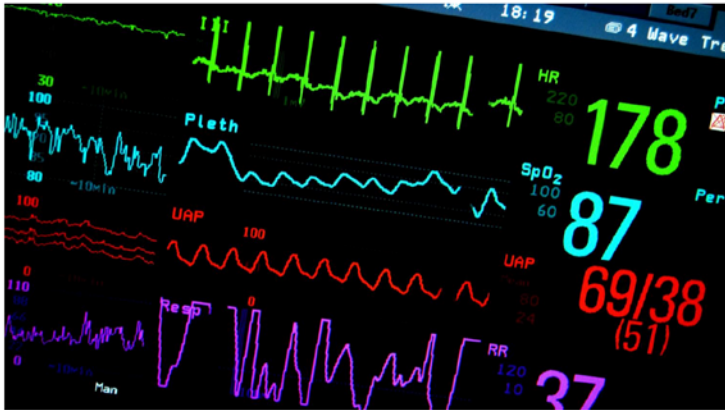
26.01.2018 07:00 Uhr

## Forschung: Künstliche Intelligenz sagt den Todeszeitpunkt voraus

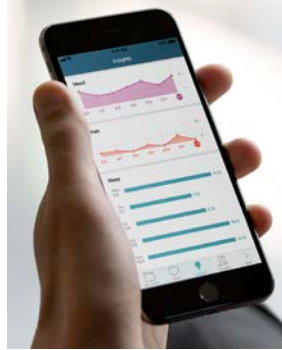
Mit Hilfe von hunderttausenden Patientendaten haben Forscher neuronale Netze trainiert, die vierundzwanzig Stunden nachdem ein Patient in ein Krankenhaus eingewiesen wird, seinen wahrscheinlichsten Todeszeitpunkt voraussagen können.

von Fabian A. Scherschel

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## ePA/ PDMS



Research Kit / Care Kit

PatientAssist 

d.velop

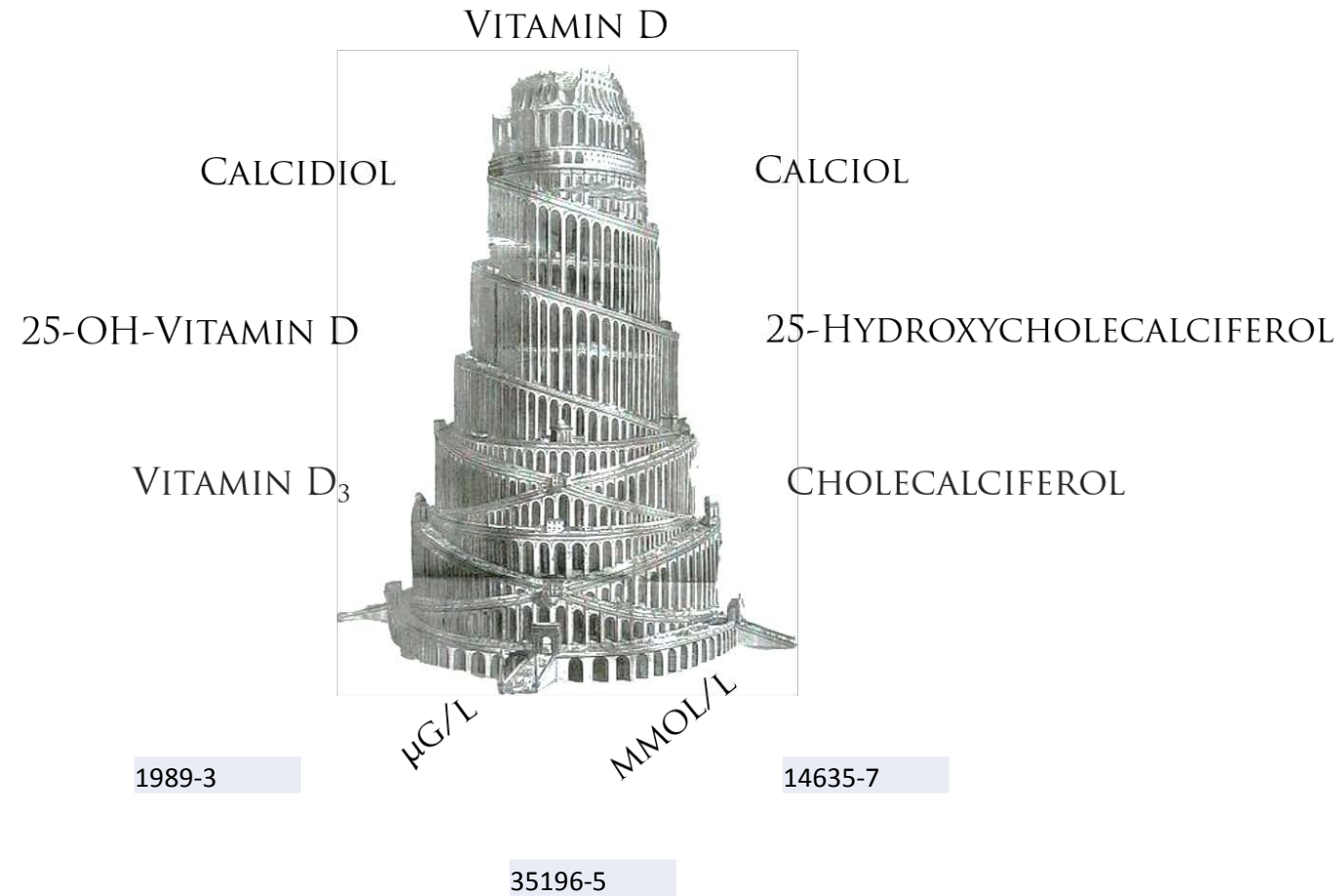
  
Vivy

Meine Gesundheitsakte Digital  
(Bayern)

Data Warehousing

## Improving Palliative Care with Deep Learning

Anand Avati\*, Kenneth Jung†, Stephanie Harman‡, Lance Downing†, Andrew Ng\* and Nigam H. Shah†



$^3\text{H}$ -basierte Radioreceptor Assay  
(RRA)-HPLC



LC-MS/MS

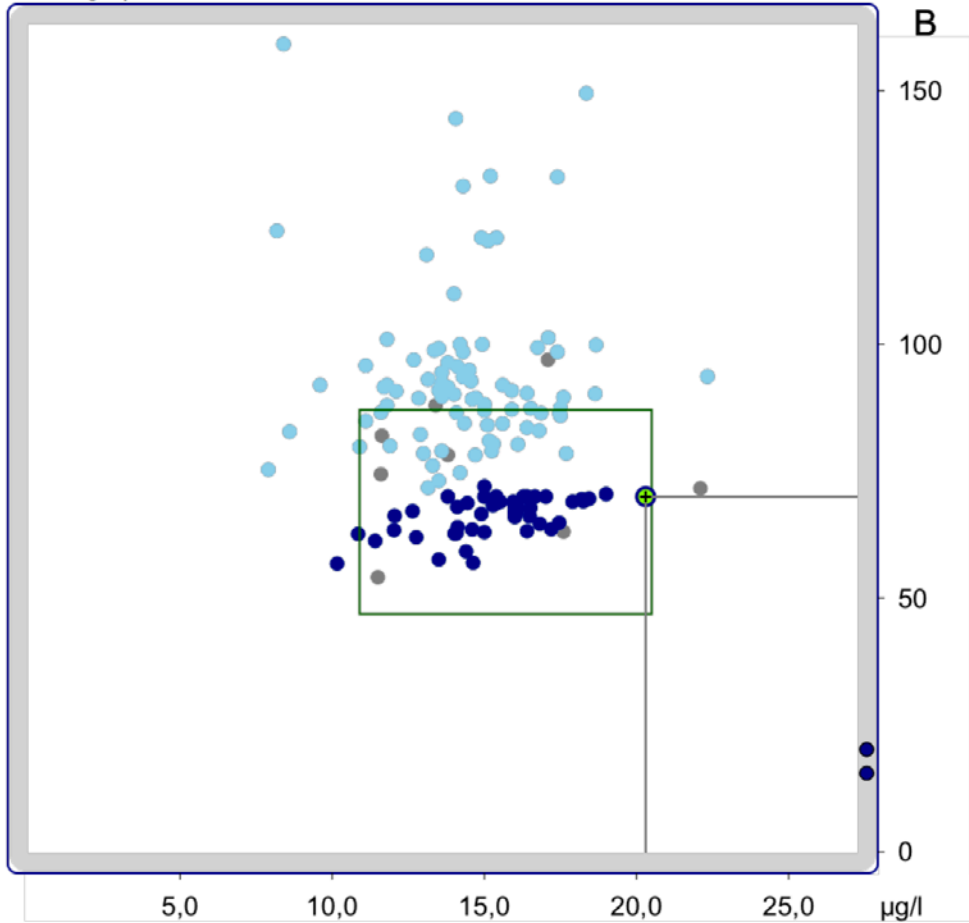
> 6 immunologische Messverfahren

Analyt **Vitamin D, total**

Methode Alle Methoden

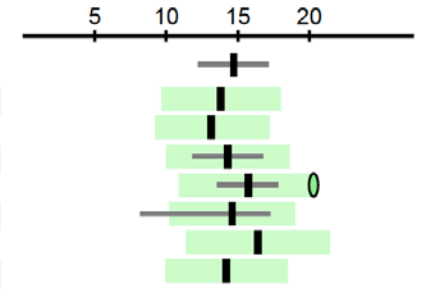
Erfolgsquote 91,6 %

Ausreisser 2



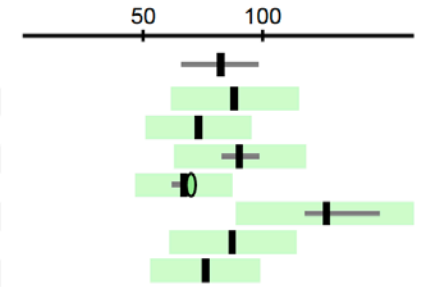
### Probe A [ $\mu\text{g/l}$ ]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		144	7.90	12.2	14.7	17.2	68.0
1	53	3	13.4		13.8		17.1
4	13	3	13.0		13.2		13.5
4	30	63	8.60	11.8	14.3	16.8	22.3
Roche2	50		10.2	13.5	15.7	17.8	68.0
Roche3	12		7.90	8.20	14.6	17.2	18.4
4	40	3	15.9		16.4		17.5
4	77	3	13.3		14.2		14.7



### Probe B [ $\mu\text{g/l}$ ]

M	Kit	N	Min	16.P	50.P	84.P	Max
Alle		144	15.5	66.1	82.5	98.2	159
1	53	3	78.2		88.0		97.0
4	13	3	71.7		73.1		78.5
4	30	63	78.5	82.8	90.2	98.5	110
Roche2	50		15.5	62.1	67.0	70.0	72.0
Roche3	12		75.3	118	127	149	159
4	40	3	86.0		87.2		90.4
4	77	3	74.7		76.1		78.2



Die Abweichung Ihrer Ergebnisse vom Median des zugehörigen Unterkollektives (Kit) beträgt:

A 29 %  
B 4.5 %

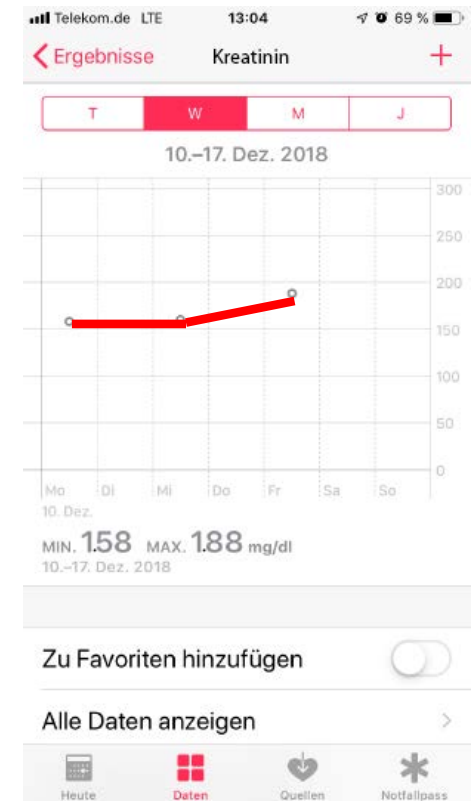
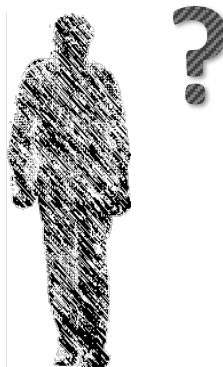
Andere Kits (Anzahl):

1-41(1), 1-111(1), 2-270(1), 3-21(2), 4-23(1), 4-99(1),

# Beispiel Kreatinin (Nierenfunktion)

Serum eines 65a Patienten wurde aliquotiert und in 4 verschiedene Laboratorien zur Analyse versendet

	Conventional result (RI) unit
Lab 1 (Enzymatisch, 14682-9)	140 (64-104) $\mu\text{mol/l}$
Lab 2 (Enzymatisch, 2160-0)	1.58 (0.72-1.18) mg/dl
Lab 3 (Jaffe, kompensiert, 2160-0)	1.60 (0.74-1.20) mg/dl
Lab 4 (Jaffe, nicht- kompensiert, 2160-0)	1.88 (1.02-1.48) mg/dl



# Voraussetzungen, um Labordaten auszuwerten?

Konstante  
Messbedingungen

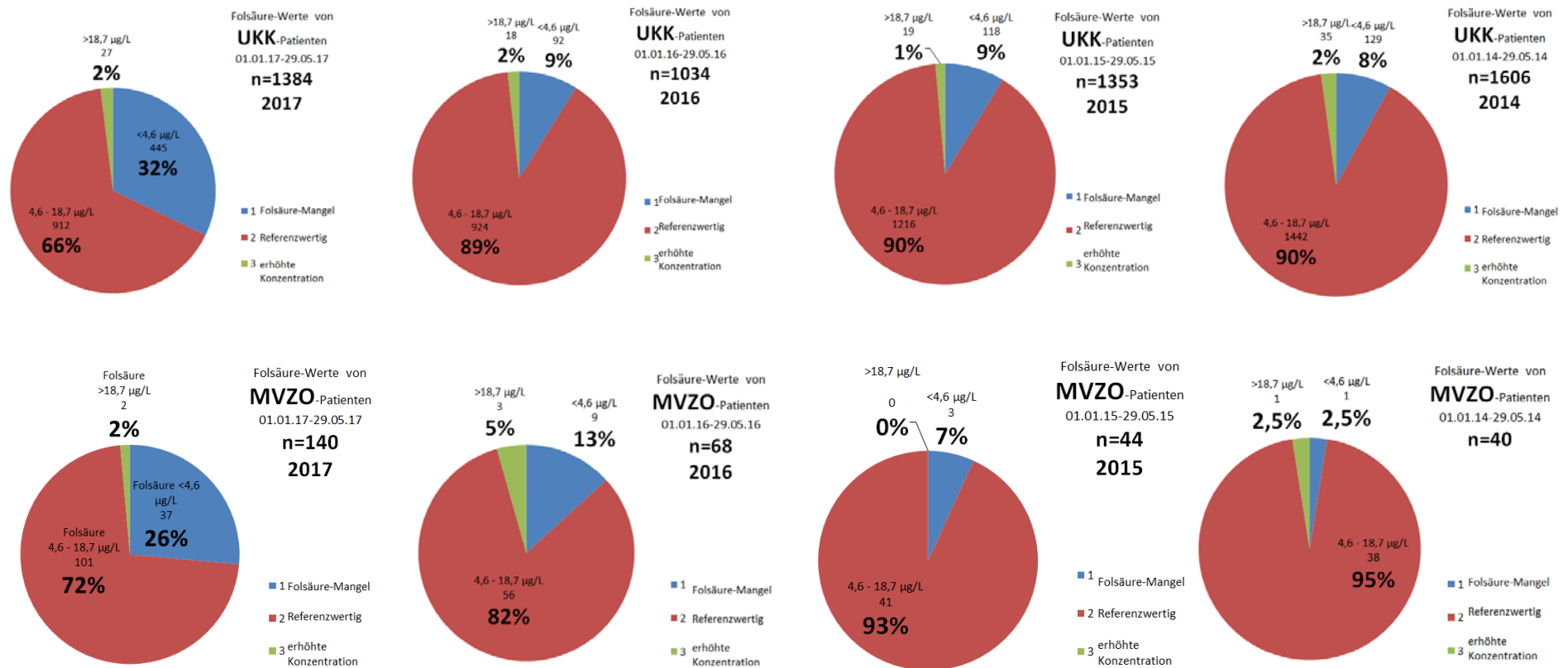
Eindeutige Informationen  
zur Messgröße (Bezeichnung)

**STANDARDISIERUNG**



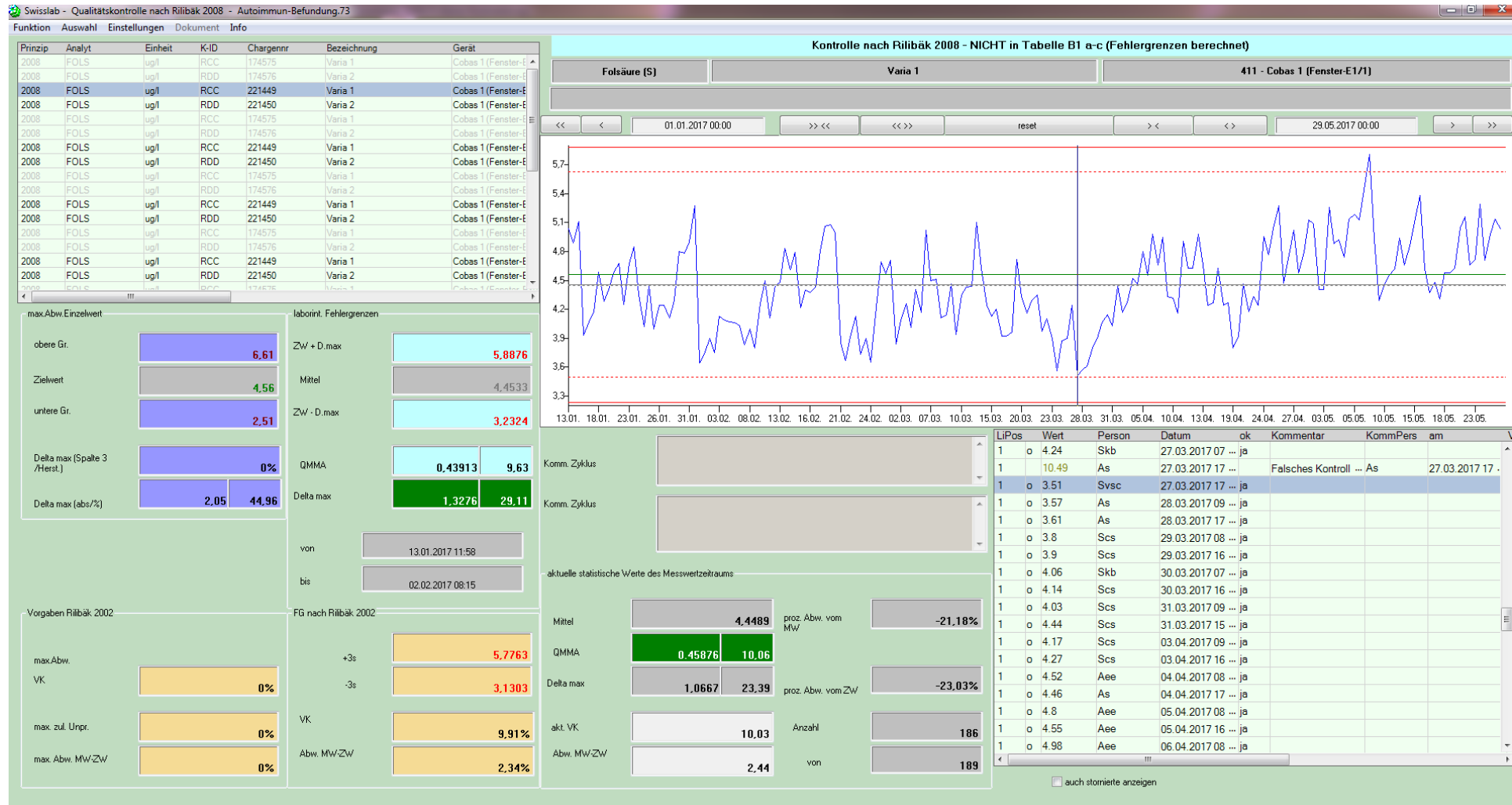
# Beispiel – Folsäure

FOLS-Mangel <4,6 µg/L	2017	2016	2015	2014
UKK	32 %	9 %	9 %	8 %
MVZO	26 %	13 %	7 %	2,5 %

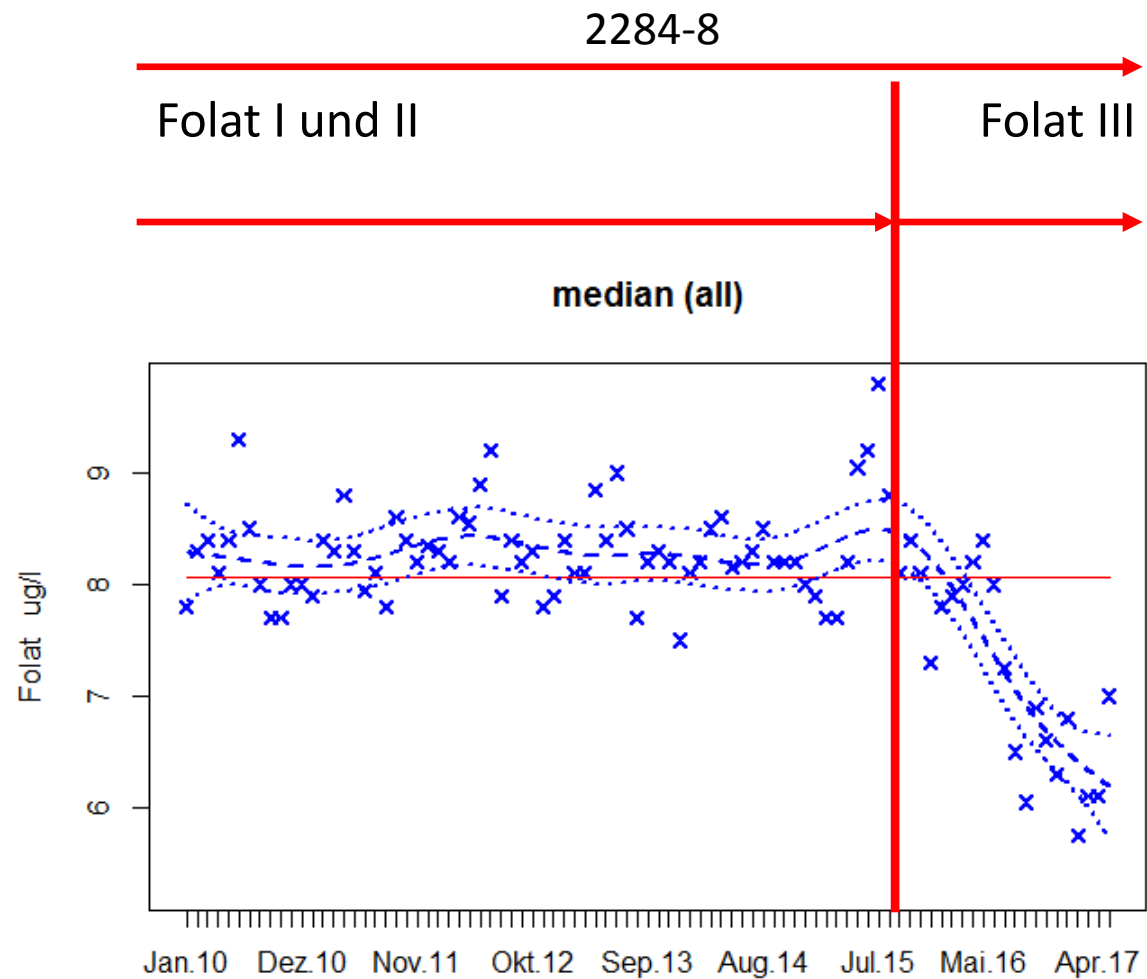


# Beispiel – Folsäure

## QK: niedrige Folsäure-Kontrolle Jan.2017 – Jun.2017 ok!

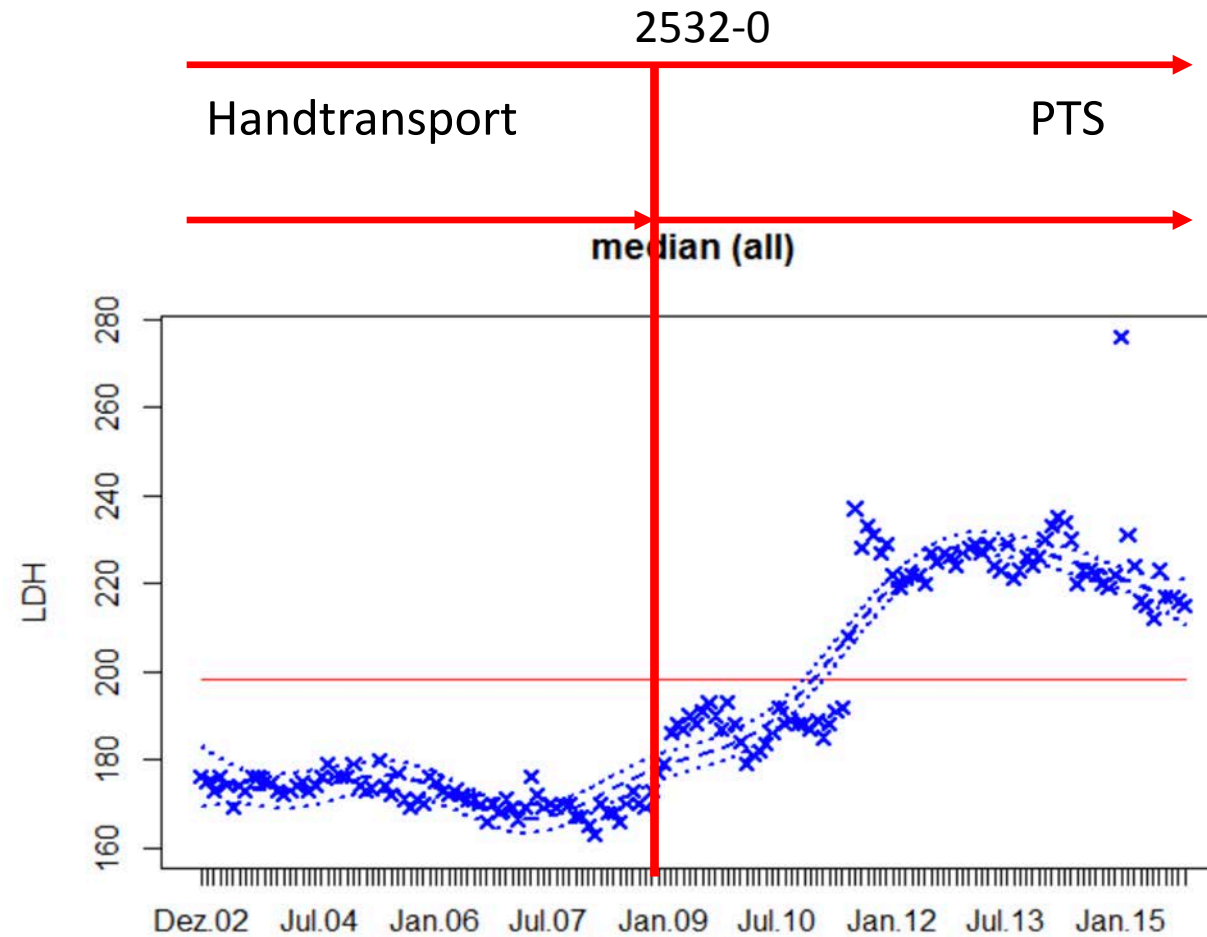


# Beispiel – Folsäure Driftanalyse



*fitted smooth-function, median=function(time), for all (blue-dashed) with CI (blue-dotted)  
compared with non time-dependent median (red).*

# Beispiel – Präanalytik Driftanalyse



*fitted smooth-function, median=function(time), for all (blue-dashed) with CI (blue-dotted)  
compared with non time-dependent median (red).*

# Minimale Information zu Laboranalytik (MILA)

- Eindeutige Analytbezeichnung / LOINC
- Mess-System (Material)
- Resultat
- Einheit
- Referenzbereich
- Zeitstempel der Anforderung und Analyse
- Patientenbezogene Daten:
  - Alter, Geschlecht (ggfs. Name und DOB)
- Ort / Herkunft der Daten (analysierendes Labor)

# FDA – LOINC?

## **B. Should manufacturers include LOINC codes in device labeling?**

FDA supports the voluntary inclusion of LOINC codes for IVD tests in labeling if the information is accurate and consistent with the approved or cleared indications for the device.

## **Logical Observation Identifiers Names and Codes for *In Vitro* Diagnostic Tests**

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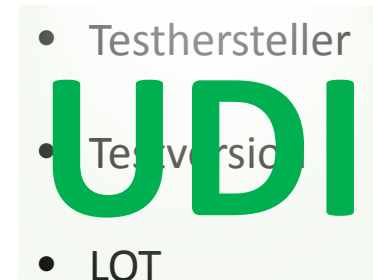
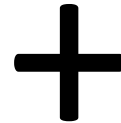
### **Guidance for Industry and Food and Drug Administration Staff**

**Document issued on June 15, 2018.**

For questions about this document, contact the Digital Health Unit in the Office of the Center Director at (301) 796-6900 or email: [DigitalHealth@fda.hhs.gov](mailto:DigitalHealth@fda.hhs.gov).

# Minimale Information zu Laboranalytik (MILA)

- Eindeutige Analytbezeichnung / LOINC
- Mess-System (Material)
- Resultat
- Einheit
- Referenzbereich / Entscheidungsgrenze
- Zeitstempel der Anforderung und Analyse
- Patientenbezogene Daten:
  - Alter, Geschlecht (ggfs. Name und DOB)
- Ort / Herkunft der Daten (analysierendes Labor)



- ...
- QK (intern/ extern)

# UDI - Unique Device Identification



(01)4015630001576(10)1245678(17)131231  
= GTIN + Batch / Lot Number + Expiration Date

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## Device Identifier – Mandatory for ALL materials

AI*	Description	Maximum Data Length
(01)	Global Trade Item Number (GTIN)	14 (numeric)

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## Product Identifier – Mandatory if applicable (Device traceability settings)

AI	Description	Maximum Data Length
(10)	Batch / Lot Number	14 (alphanumeric)
(17)	Expiration Date	6 (YYMMDD)
(21)	Serial Number	18 (alphanumeric)





## Unique Device Identification System

A Rule by the [Food and Drug Administration](#) on [09/24/2013](#)

**PUBLISHED DOCUMENT**

Start Printed Page 58786

**AGENCY:**  
Food and Drug Administration, HHS.

**ACTION:**  
Final rule.

**SUMMARY:**  
The Food and Drug Administration (FDA) is issuing a final rule to establish a system to adequately identify devices through distribution and use. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI will be required to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

**DOCUMENT DETAILS**

**Printed version:**  
[PDF](#)

**Publication Date:**  
09/24/2013

**Agencies:**  
[Food and Drug Administration](#)

**Dates:**  
This rule is effective December 23, 2013, except Sec. Sec. 801.55, 830.10, 830.100, 830.110, 830.120, and 830.130 are effective October 24, 2013. The incorporation by reference of Sec. 830.20 listed in the rule is approved by the Director of the Office of the Federal Register as of December 23, 2013. The incorporation by reference of Sec. Sec. 830.10 and 830.100 listed in the rule is approved by the Director of the Office of the Federal Register as of October 24, 2013. Certain provisions have later compliance dates as discussed in section VII. B. "Compliance Dates."

**Effective Date:**  
12/23/2013

# UDI - Datenbanken

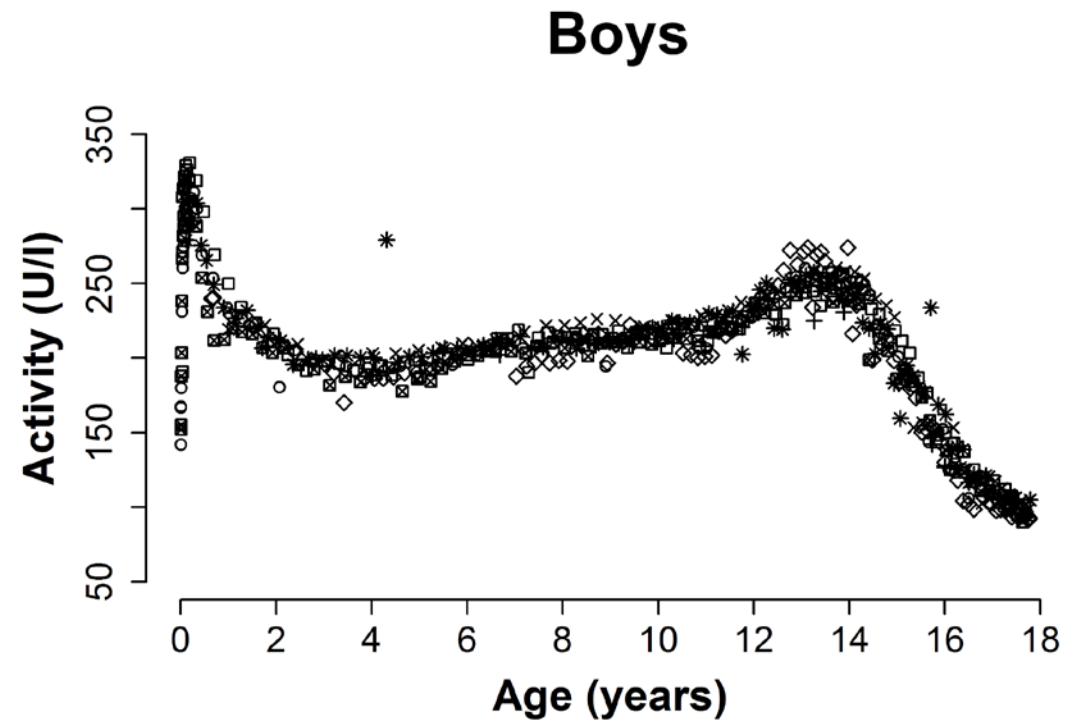
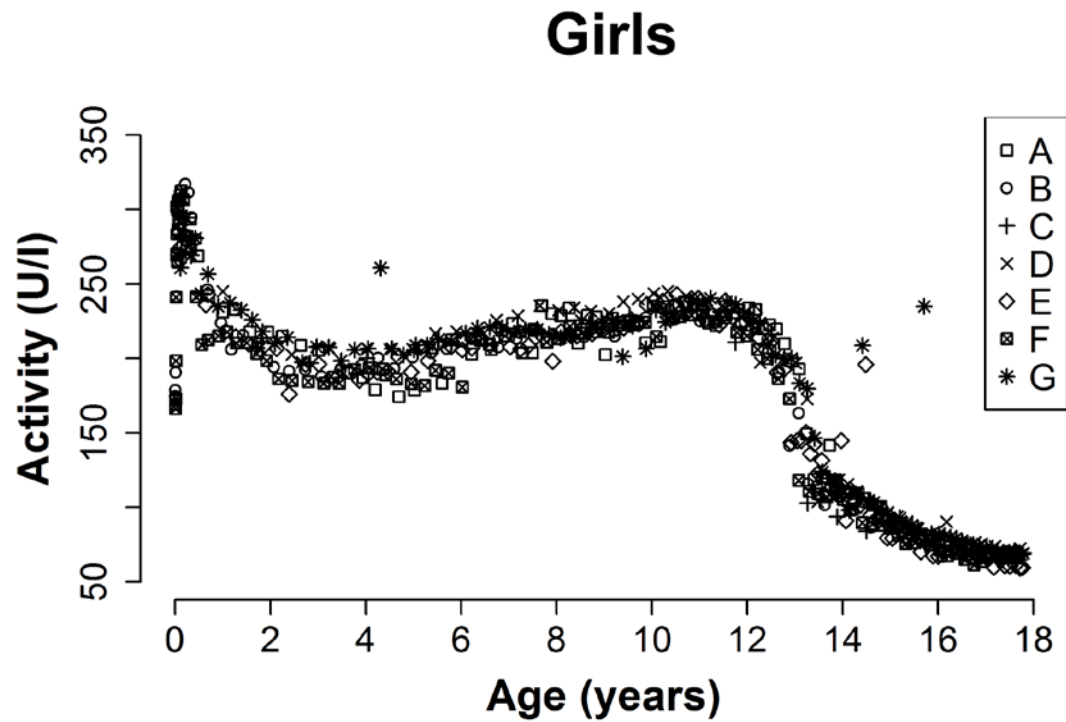
 U.S. NATIONAL LIBRARY OF MEDICINE

ACCESS  
**GUDID**  
IDENTIFY YOUR MEDICAL DEVICE



Kann man denn Labordaten überhaupt  
auswerten?

# AP – Poolen von Daten

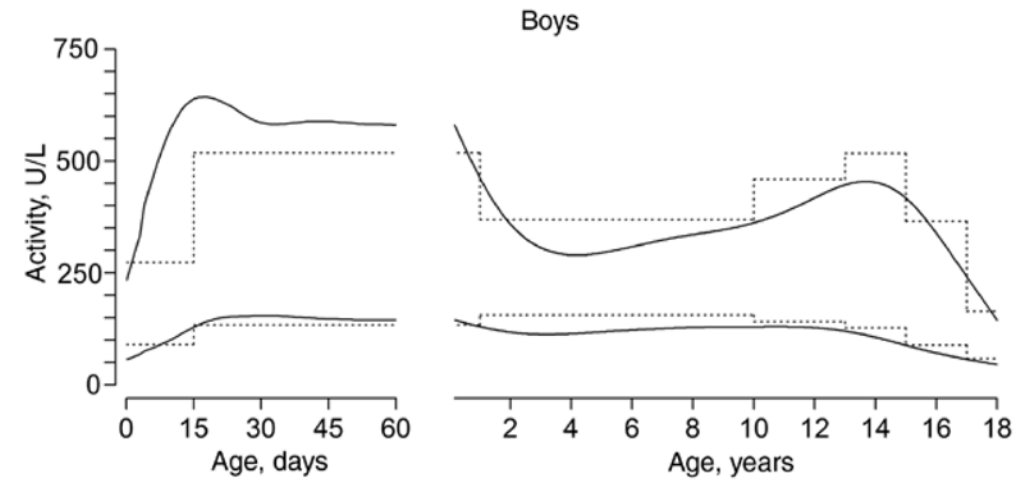
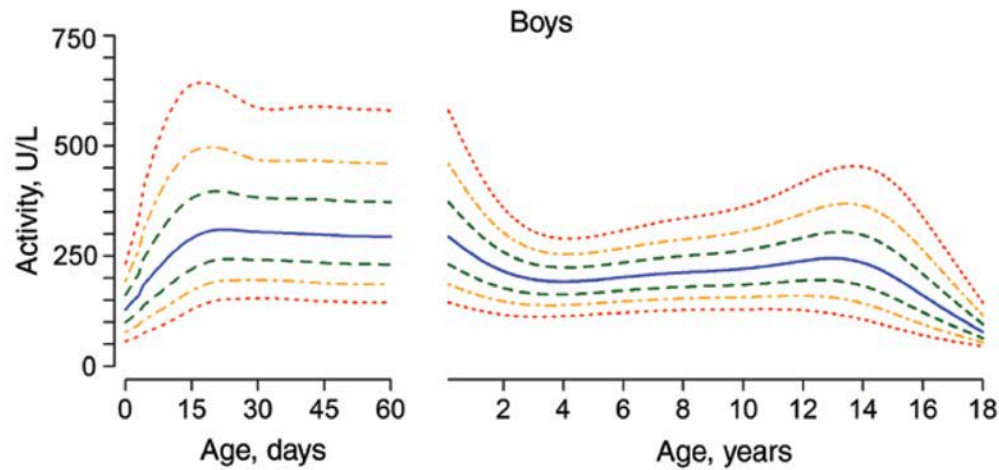
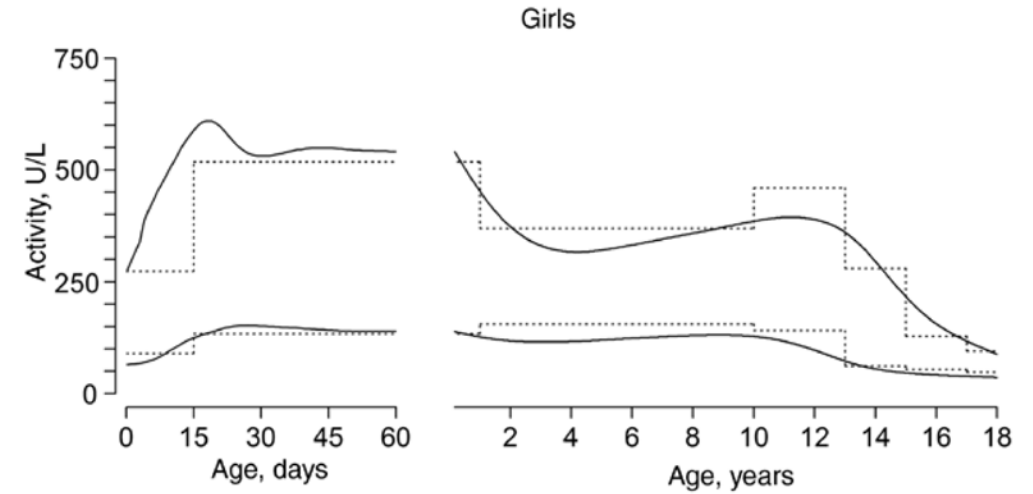
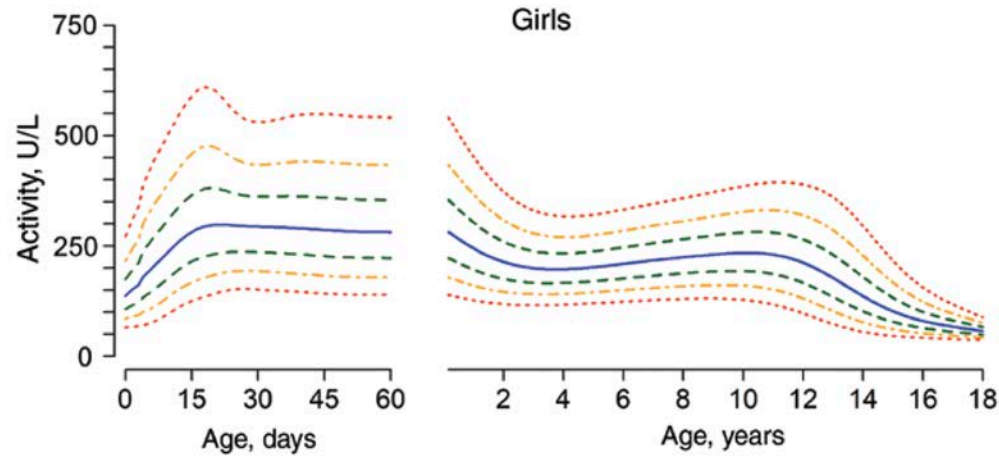


# AP – Poolen von Daten

## Datensätze

Age group	Total		Boys		Girls	
	Samples	Individuals	Samples	Individuals	Samples	Individuals
0–28 days	11,513	7823	6723	4449	4790	3374
29 days to 1 year	30,780	10,924	17,422	6148	13,358	4776
1 year	18,076	7393	9668	3959	8408	3434
2 years	15,817	6605	8857	3566	6960	3039
3 years	15,456	6899	8572	3811	6884	3088
4 years	15,246	7389	8452	4111	6794	3278
5 years	15,396	7844	8502	4324	6894	3520
6 years	15,579	7646	8796	4159	6783	3487
7 years	15,617	8022	7999	4237	7618	3785
8 years	16,251	8624	8518	4475	7733	4149
9 years	16,679	8942	8999	4690	7680	4252
10 years	17,468	9526	9386	5055	8082	4471
11 years	18,212	9892	9678	5314	8534	4578
12 years	19,677	10,833	10,744	5777	8933	5056
13 years	22,361	12,279	11,486	6355	10,875	5924
14 years	23,580	12,304	11,950	6223	11,630	6081
15 years	23,191	11,884	11,397	5705	11,794	6179
16 years	25,196	12,336	13,093	5731	12,103	6605
17 years	25,237	12,312	12,699	5577	12,538	6735
Total	36,1405	12,4440	19,2972	64,670	16,8433	59,770

# AP – Pädiatrische RI



Age- and sex-dependent percentile charts for alkaline phosphatase activity, showing the 50th percentile (solid lines, blue), 25th and 75th percentiles (dashed lines, green), 10th and 90th percentiles (dashdotted lines, orange), and 2.5th and 97.5th percentiles (dotted lines, red);

Comparison of 2.5th and 97.5th percentiles for alkaline phosphatase activity (solid lines) to reference intervals from the CALIPER study (dotted lines)

# Minimale Information zu Laboranalytik (MILA)

## LOINC.

- Eindeutige Analytbezeichnung / LOINC
- Mess-System (Material)
- Resultat
- Einheit
- Referenzbereich / Entscheidungsgrenze
- Zeitstempel der Anforderung und Analyse
- Patientenbezogene Daten.
  - Alter, Geschlecht (ggfs. Name und DOB)
- Ort / Herkunft der Daten (analysierendes Labor)

+

+

- Testhersteller

## UDI

- Testversion
- LOT

## Standard- information

Danke!