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Critical success factors for introducing and operating a CDSS

- lessons learned …

Dr. Matthias Sonnenschein, Manager Business Strategy – Public Affairs

HCI Solutions, a company of the Galenica Group

≡ HCI Solutions

Disclosure

− working and living in Switzerland, born grown up in Germany

− PhD in Developmental Biology Scientific librarian

− 30 years in the healthcare sector

− Employer: HCI Solutions AG in Berne since 1995

− HCI: master data for the Swiss healthcare market and a medical device for quality assurance in medication

HCI is a company of the Galenica Group: wholesaler, pharmacy chain, producer/vendor of OTC drugs

− © HCI Solutions

Disclosure

HCI Solutions:

Collects data from
- Authorities (nat./international)
- Pharmaceutical companies
- Universities /Associations
- Hospitals
- Scientific publications

Creates Databases, combining
- commercial and scientifc data
- highly structured and coded
- french & german

Distribution to the Swiss market
- via > 170 software vendors

HCI databases / services are used
- hospitals and nursing homes
- pharmacies, medical centers
- wholesalers
- Insurance companies

Operates a CDS System
- as a Class 1 medical device
- as plug-in / Webservice

Scope of the presentation

– Clinical Decision Support Systems

  – with focus only on medication

  – no consideration neither of integrated guidelines
    nor pharmaceutical intervention
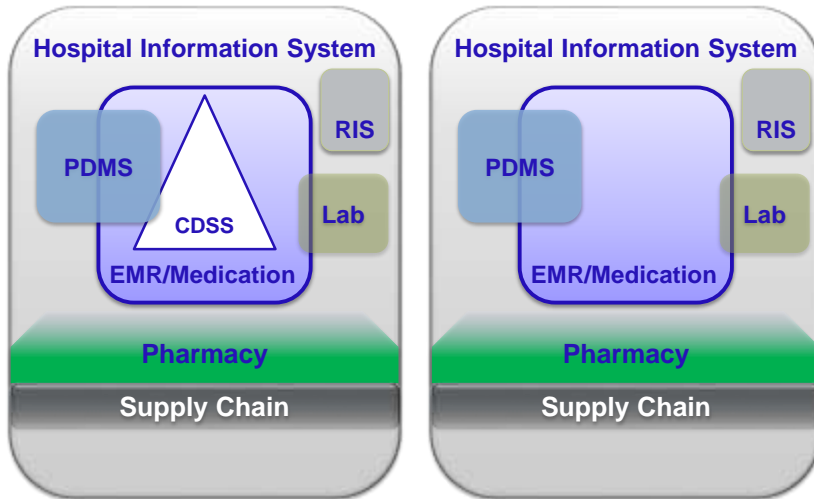
  – focus on process integrated solutions

Clinical Decision Support – not a Solitaire…
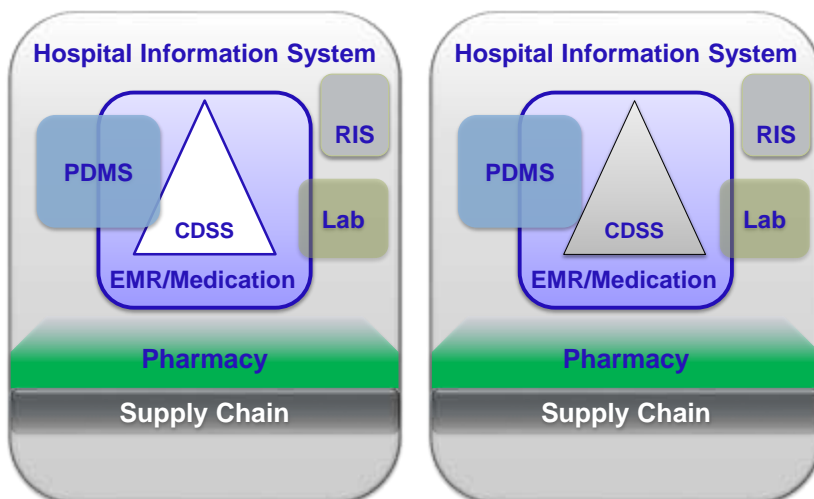
Clinical Decision Support – … embedded in a complex environment

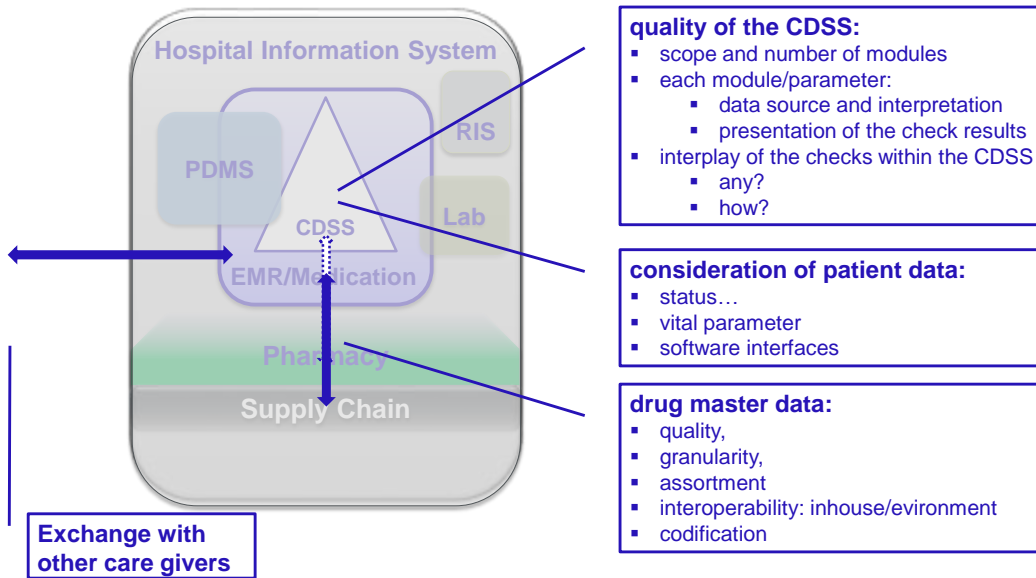## Clinical Decision Support – … embedded in a complex environment

Clinical Decision Support – embedded in a complex environment

Succes factors
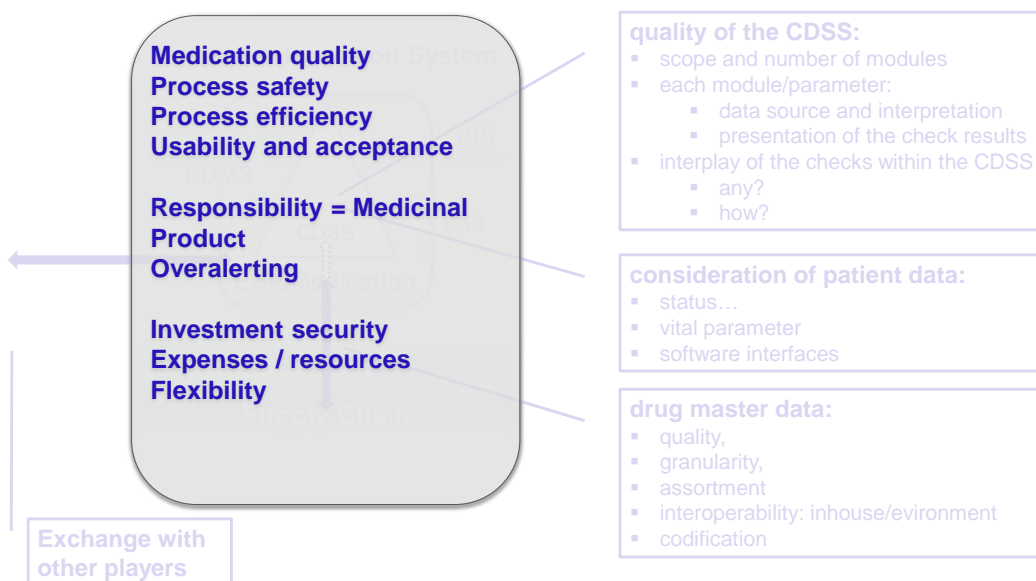
Hospital Information System

RIS

PDMS

CDSS

Lab

EMR/Medication

Pharmacy

Supply Chain

Exchange with other care givers

– © HCI Solutions

quality of the CDSS:
- scope and number of modules
- each module/parameter:
  - data source and interpretation
  - presentation of the check results
- interplay of the checks within the CDSS
  - any?
  - how?

consideration of patient data:
- status…
- vital parameter
- software interfaces

drug master data:
- quality,
- granularity,
- assortment
- interoperability: inhouse/evironment
- codification

Succes factors → *influencing*

Medication quality
Process safety
Process efficiency
Usability and acceptance

Responsibility = Medicinal Product
Overalerting

Investment security
Expenses / resources
Flexibility

Exchange with other players

– © HCI Solutions

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Documedis® for illustration, as a model

Drug master data file and data management

− Data model with support of supply chain as well as medication processes

− Rules and (automatic) support
 - for the substitution of drugs
 - hospital admission/discharge

− Medicines commercially available and approved by the authorities as well as
  - imported drugs
  - self-manufactured drugs
in the same database?!

SANDIMMUN NEORAL Kaps 10 mg
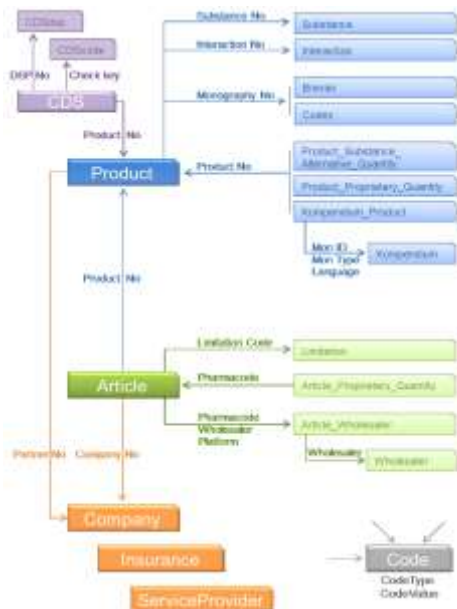Novartis Pharma Schweiz AG

Blister 60 Stk

Data model:
Support of supply chain as well as medication?

medication, CDSS

supply chain,

billing, reimboursement

SANDIMMUN NEORAL Kaps 10 mg
Novartis Pharma Schweiz AG

Blister 60 Stk

Data model:
Support of supply chain as well as medication?

SANDIMMUN NEORAL Kaps 10 mg
Novartis Pharma Schweiz AG

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Drug master data file and data management

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Drug master data file and data management

– Rules and (automatic) support
  - for the substitution of drugs
  - hospital admission/discharge

○ Metformin Helvepharm Filmtabl 1000 mg
  is not in stock

Proposal:
Substitution with
☆ Glucophage Filmtabl 1000 mg

Drug master data file and data management

− Medicines commercially available and
 approved by the authorities *as well as*
  - imported drugs
  - self-manufactured drugs
in the same database?!

Morphin HCl Inj. Sol. 100mg/20 ml (Hosp XY)

Mouse over:
«unidentified medicinal product»

Übersicht

Medicine											
Morphin HCL Inj. Sol. 100mg/20 ml (Hosp XY)	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	⊖	∧
Nexium Mups Tabl 20 mg / Esomeprazol	⚠	✓	✓	⚠	✓	⚠	✓	⚠	✓	⚠	∨
Seralin-Mepha Lactab 50 mg / Sertalin	❗	✓	✓	✓	✓	⚠	⚠	⚠	❗	⚠	∨
Beloc Zok Ret Tabl 200 mg / Metoprolol tartrat	⚠	✓	✓	✓	◍	✓	✓	✓	✓	⚠	∨
Cip eco Filmtabl 250 mg / Ciprofloxacin	✖	✓	✓	✓	✓	⚠	✓	⚠	❗	❓	∨
Adartrel Filmtabl 0.25 mg / Ropinirol	⚠	✓	✓	✓	✓	✖	✖	✓	⚠	⚠	∨
Sirdalud Tabl 2 mg / Tizanidin	✖	✓	✓	✓	✓	⚠	◍	⚠	⚠	⚠	∨
Motilium Filmtabl 10 mg / Domperidon	❗	✓	✓	✓	✓	⚠	✓	⚠	✓	✓	∨
Amiodaron-Mepha Tabl 200 mg											

Codification of self-manufactured and imported drugs
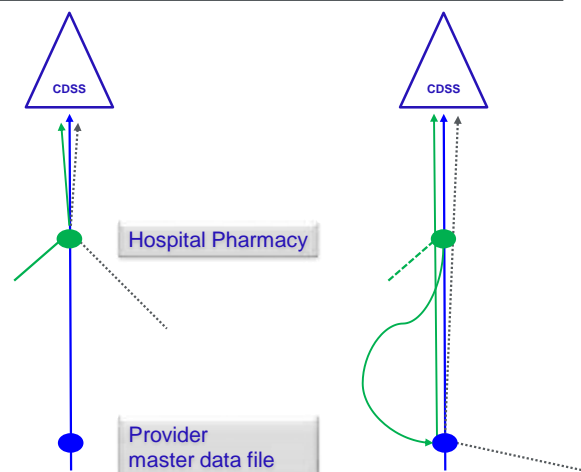

imported

«normal»

Drug master data file and data management

– Data model with support of supply chain as well as medication processes

– Rules and (automatic) support
  - for the substitution of drugs
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– Medicines commercially available and approved by the authorities as well as
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in the same database?!

CDSS

CDSS

Hospital Pharmacy

Provider
master data file

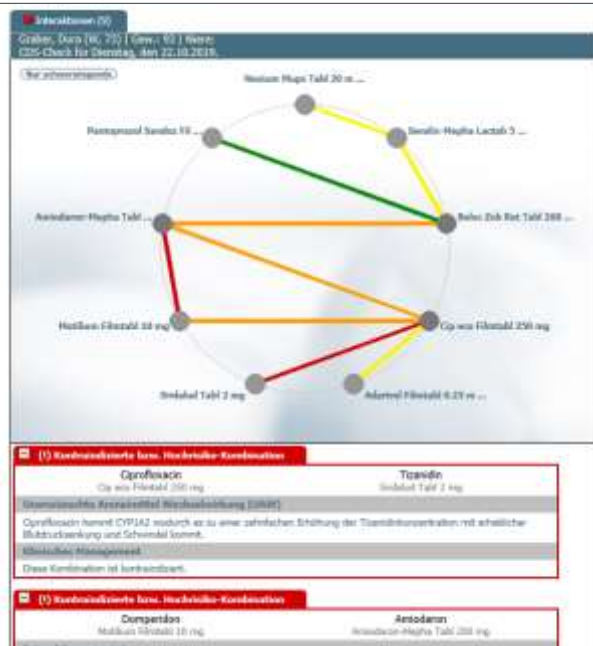## CDSS like a navigation system

…following «signals»:

– which parameters are included?

– are they up to date?

– are they dynamic?

– are there too many signals?

– are they understandable?

CDSS like a navigation system

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– are they understandable?

Flycicle® CH
(University of Heidelberg/
Dosing GmbH)

CDSS like a navigation system

	Flycicle D	Flycicle CH
Contraindicated, high risk		
Attention, serious risk		
Caution, small risk		
Light, rarely clinical relevant		
No risk		
Missing data recorded		
No data available in ...		
No information available		
Contradictory scientific data		
Technical malfunction		

Flycicle® CH
(University of Heidelberg/
Dosing GmbH)

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Documedis® CDS-Check – clear, unambiguous visual warnings

colour + icons = appropriate for colourblind people

Contraindicated very high risk	Attention, serious risk	Caution, small risk	No risk

Missing data recorded	No data available in Documedis	No information available	Contradictory scientific data	Technical malfunction

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Documemedis® CDS-Check – clear icons

| Allergy of active ingredients | Allergy of excipients | Doping | (Maximum) Dosage | Double medication | Advanced age | Driving vehicles |

| Liver insufficiency | Food interaction | Renal insufficiency | Reproduction | D-D Interactions | D-D Interactions Flycicle |
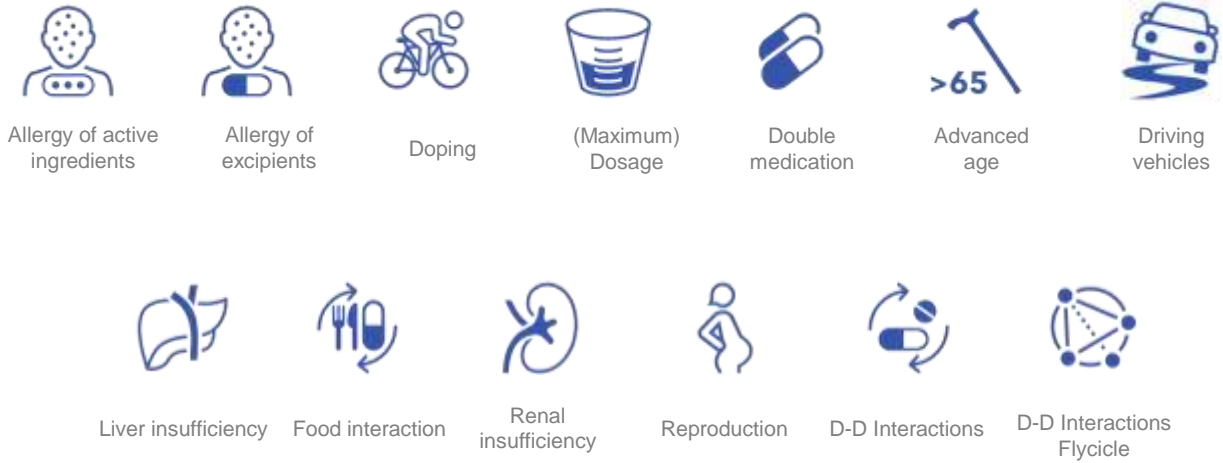
Gentle pressure on software partners
→ to adopt a defined stylistic language

→ **medical device software:** HCI takes the responsibility also for the visual response to the checks
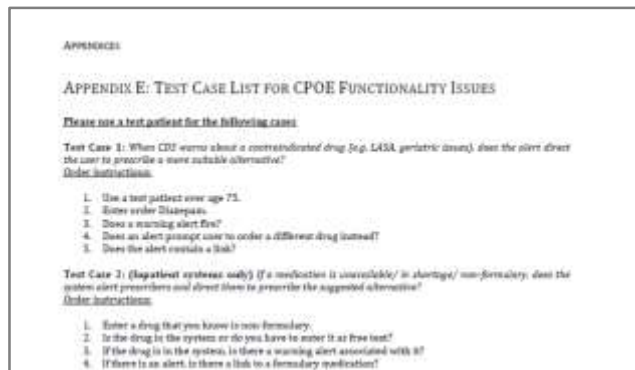
On the other hand:
→   flexible interface for software partners

Diabetes   Pharmacogenomics

→ **medical device software:** HCI takes the responsibility also for the visual response to the checks

Test cases for evaluation of approate partners …

Test cases for evaluation …and **responsibility**!!

CDSS: are the responses dynamic?   - or only post festum ?

CDSS: are the responses dynamic?   - or only post festum ?

DOXYCLIN FORTE TABL ZOG..

VIBRAVENÖS INJ LÖS 100 m..

FERRO SANOL KAPS 100m..

CDSS: are the responses dynamic?   - or only post festum ?

Doxcyclin per Injection +
Ferrum oral reduces the
interaction risk

DOXYCLIN FORTE TABL ZOG..

VIBRAVENÖS INJ LÖS 100 m..

FERRO SANOL KAPS 100m..

Level of evidence

– SPC

– Expert analysis

– Evidence based
  analysis

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CDSS is a medical device software (MDSW)

Over alerting

→ **Who is resposible in case of
   changing the alerts?**
→ Provider?
→ Hospital?

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Overriding alerts…

Research and applications

Overrides of medication-related clinical decision
support alerts in outpatients

Karen C Nanji,[1,2,3] Sarah P Slight,[2,4] Diane L Seger,[5] Insook Cho,[2,4,5] Julie M Fiskio,[4]
Lisa M Redden,[3] Lynn A Volk,[5] David W Bates[2,3,4]

Results We reviewed 157 483 CDS alerts (
rate) on 2 004 069 medication orders during
period. 82 889 (52.6%) of alerts were overri
The most common alerts were duplicate drug
patient allergy (16.8%), and drug–drug inter
(15.8%). The most likely alerts to be overrid
formulary substitutions (85.0%), age-based
recommendations (79.0%), renal recommen
(78.0%), and patient allergies (77.4%). An a
53% of overrides were classified as appropri
rates of appropriateness varied by alert type
from 12% for renal recommendations to 92%
patient allergies.
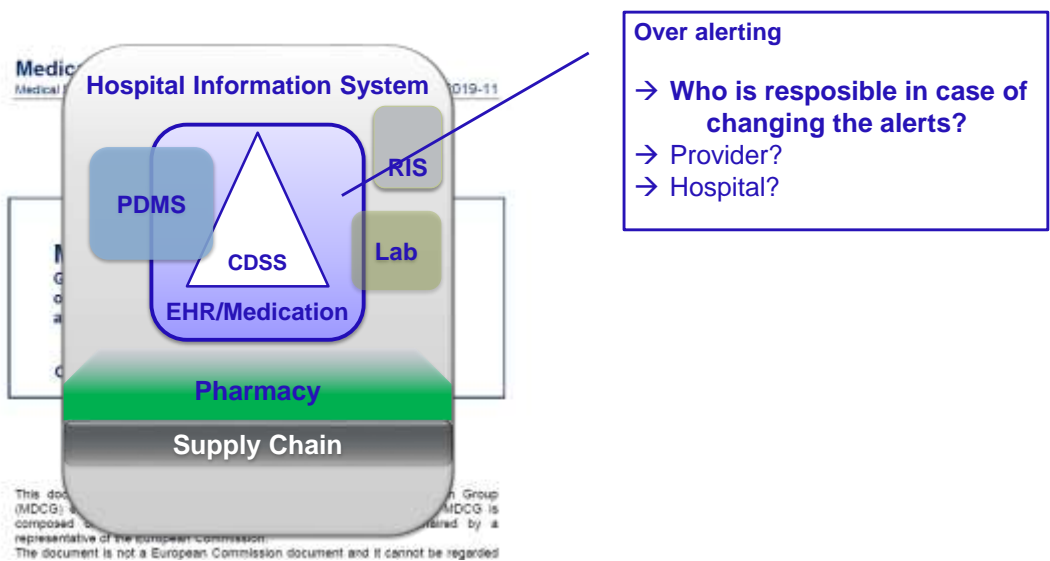
Nanji KC, et al. J Am Med Inform Assoc 2018;21:487–491

Table 1
Breakdown of alert overrides

Alert type	Total alerts N	(%)	Alert overrides N	(%)	Most common reason for override
Patient allergy	26 408	16.8	20 430	77.4	Patient took previously without allergic reaction
Drug–drug interaction	24 849	15.8	14 988	60.2	Will monitor as recommended
Duplicate drug	52 113	33.1	14 917	28.8	Patient requires different strengths of same drug
Drug-class interaction	19 593	12.4	4782	24.4	Transitioning from one drug to the other
Class–class interaction	4184	2.7	2918	69.7	Patient on long term therapy with combination
Age-based suggestion	10 501	6.7	8297	79.0	Patient has tolerated this drug in the past
Renal suggestion	3890	2.5	3036	78.0	Patient has tolerated this drug in the past
Formulary substitution	15 948	10.1	13 554	85.0	Intolerance/failure of suggested substitution
Total	157 483	100.0	82 899	52.6	

Alerting or information?

tablet can be
divided

Dora Graber   23.11.1945

CIP ECO Filmtabl 250 mg
Ciprofloxacin

Stück

Beschreibung

Unabhängig der Mahlzeiten
Erwachsene
Unkomplizierte Zystitis: 2xtgl. 250–500 mg.
Unkomplizierte Zystitis der prämenopausalen Frau, Gonorrho, Prophylaxe invasiver Infektionen durch N. meningitidis:
einmalige Dosis von 500 mg.
Milzbrand: initial i.v., dann p.o.: 2xtgl. 500 mg.
Andere Indikationen: 2xtgl. 500–750 mg eF1x

Pharmacogenomics: Alerting or information?

pharmacogenomic test recommended because of. ERBB2 (HER2) …

… an outlook: IDMP

IDMP in a Nutshell

Substances
EN ISO 11238

e.g. Paracetamol, chemical substance, manufactured in XYZ

Dose forms, etc.
EN ISO 11239

e.g. Packaging type (box, blisters), pharmaceutical dose form (oral, injection)

MPID
EN ISO 11615

e.g. Box with two blisters of 10 Tablets each

Units of measurement
EN ISO 11240

e.g. mg, ml, μg

PhPID
EN ISO 11616

e.g. Oral Tablet consist of paracetamol 200 mg per tablet

© ARCONDIS Group 2015
by courtesy of IDMP1.com

… an outlook: IDMP

e.g.
MedDRA
coded
indications

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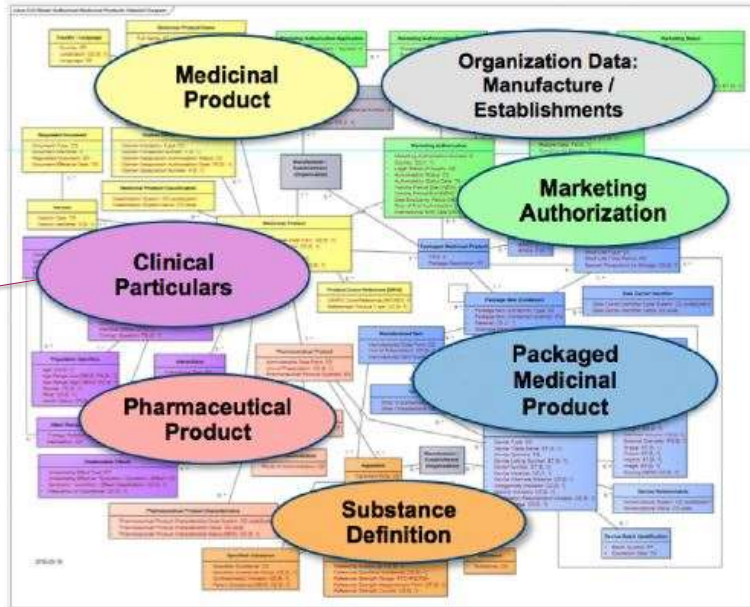
… an outlook: SNOMED CT

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… an outlook: IDMP + Snomed CT

Substances – coded according both systems

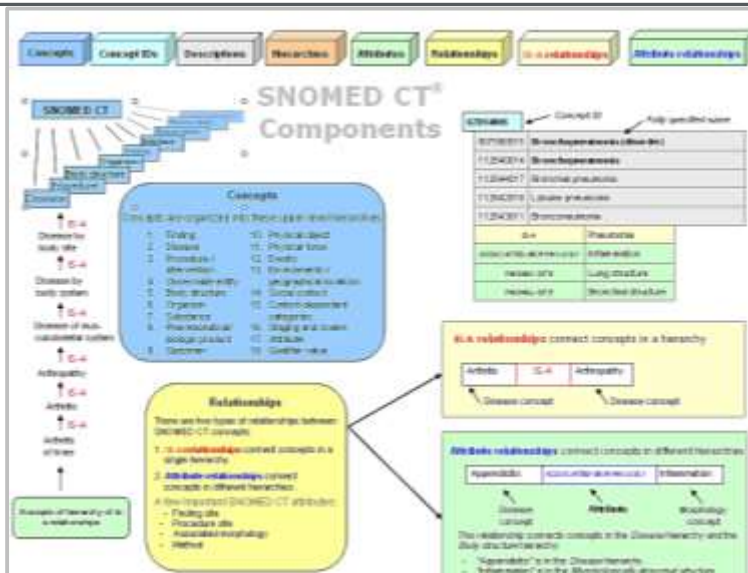| Substanz ID	HCI Substance latin	CAS	G-SRS Name = IDMP	UNII = IDMP	SNOMED Name	SNOMED ID
208077	Abacavirum	0136470-78-5	ABACAVIR	WR2TIP26VS	Abacavir (substance)	387005008
209788	Abataceptum	0332348-12-6	ABATACEPT	7D0YB67S97	Abatacept (substance)	421777009
207592	Abciximabum	0143653-53-6	ABCIXIMAB	X85G7936GV	Abciximab (substance)	386951001
212447	Abemaciclibum	1231929-97-7	ABEMACICLIB	60UAB198HK	Abemaciclib (substance)	761851004
211030	Abirateronum	0154229-19-3	ABIRATERONE	G819A456D0	Abiraterone (substance)	699678007
207580	Acamprosatum	0077337-76-9	ACAMPROSATE	N4K14YGM3J	Acamprosate (substance)	391698009
202183	Acarbosum	0056180-94-0	ACARBOSE	T58MSI464G	Acarbose (substance)	386965004
200005	Acemetacinum	0053164-05-9	ACEMETACIN	5V141XK28X	Acemetacin (substance)	391704009
200006	Acenocoumarolum	0000152-72-7	ACENOCOUMAROL	I6WP63U32H	Acenocoumarol (substance)	387457003
200347	Acetazolamidum	0000059-66-5	ACETAZOLAMIDE	O3FX965V0I	Acetazolamide (substance)	372709008
200351	Acetylcysteinum	0000616-91-1	ACETYLCYSTEINE	WYQ7N0BPYC	Acetylcysteine (substance)	387440002
200007	Aciclovirum	0059277-89-3	ACYCLOVIR	X4HES1O11F	Aciclovir (substance)	372729009
200357	Acidum acetylsalicylicum	0000050-78-2	ASPIRIN	R16CO5Y76E	Aspirin (substance)	387458008
207636	Acidum alendronicum	0066376-36-1	ALENDRONIC ACID	X1J18R4W8P	Alendronic acid (substance)	391730008
211375	Acidum aminolevulinicum	0000106-60-5	AMINOLEVULINIC ACID	88755TAZ87	5-aminolevulinic acid (substance)	259496005
203968	Acidum ascorbicum (Vitamin C, E300)	0000050-81-7	ASCORBIC ACID	PQ6CK8PD0R	Ascorbic acid (substance)	43706004
200021	Acidum asparticum	0000056-84-8	ASPARTIC ACID	30KYC7MIAl	Aspartic acid (substance)	44970006

Example Allergy → in future also coded with SNOMED

SNOMED CT

- Pyrazole (substance)

- Allergy to analgesic (finding)

Wirkstoff-Allergien
Allergien : Analgetika-Allergie (Pyrazolon-Typ)

spec. allergy

severity level 1

severity level 2

drug

drug

Novalgin Filmtabl 500 mg
Metamizol natrium-1-Wasser

Celebrex Kaps 200 mg
Celecoxib

Analgetika-Allergie /...

![eMediplan] **eMediplan**

Der Schweizer Medikationsplan

Doris Graber
23.03.1950 (W)
Rue Chante, 1200 Genf / +41 79 123 45 67

Körpergrösse / Gewicht: 165 cm / 71 kg
Niereninsuffizienz: leicht
Allergie(n): Penicillin-Allergie

erstellt von:

Dr. Hans Kauf
Effingerstrasse
3011 Bern

Letzter Stand: 25.08.2017 09:34

Medikament		Morgen	Mittag	Abend	zur Nacht	Einheit	Art der Medikation	Von bis u. mit	Anleitung	Grund	Verordnet durch
CIPROXIN Lacktabl 500 mg Ciprofloxacin		1	-	1	-	Stück	täglich	25.08.2017 03.09.2017	nach dem Essen	Infektion	Dr. Hans Kauf, Bern
CO-DIOVAN Filmtabl 160/12.5 mg Valsartan, Hydrochlorothiazid		1	-	-	-	Stück	täglich			Bluthochdruck	Dr. Eric Dubois, Genf
SORTIS Filmtabl 20 mg Atorvastatin		-	-	1	-	Stück	täglich			Cholesterinsenker	Dr. Eric Dubois, Genf
SERESTA Tabl 15 mg Oxazepam		-	-	-	1	Stück	täglich			Beruhigung	Dr. Eric Dubois, Genf

Reservemedikation

| PANADOL S Filmtabl 500 mg Paracetamol | | siehe Anleitung | | | | | | | bis zu max. 4 mal täglich 1 Tablette einnehmen | Schmerzen | Selbstmedikation |

Bemerkung :

Die Patientin ist vom eMediplan begeistert!