Workshop Data Management

MedCODES, MARVIN und das Management der Daten

Agenda

- Doku-Reports
- MARVIN – Data Changes
- Adverse Events der Weg aus der Akte in die Analyse

GBG
GERMAN
BREAST
GROUP

Doku-Reports

	EOT																												FU 01					FU 02								FU 03						
	EOTSG	EOTCb	EOTCis	EOTCap	EOTP	TREAT_Endo_EOT	TREAT_CDK46_EOT	PhyEx_EOT	Hema_EOT	BioChemistry_EOT	LabOther_EOT	CM_YN_EOT	AE01_EOT	AE02_EOT	BioM_EOT	BioMStool_EOT	FACTB_EOT	FACTCF_EOT	EQ5D5L_EOT	EOO_SOFU	CM	TROP2	BRCAResult	RF	BioM_Rel	DRF	Withdrawal	ReConsent	FU_PatStatus_01	FU_ACT_01	FU_EndoTreat_01	FU_CDK46Treat_01	FU_OtherExam_01	FU_PatStatus_02	FU_ACT_02	FU_EndoTreat_02	FU_CDK46Treat_02	FU_OtherExam_02	FACTB_FU02	FACTCF_FU02	EQ5D5L_FU02	FU_PatStatus_03	FU_ACT_03	FU_EndoTreat_03	FU_CDK46Treat_03	FU_OtherExam_03	FU_PatStatus_04	FU_ACT_04
	x					x		x	x	x	x	x	x	x	x	n.a.	x	x	x		x		x					p	x	x	x	n.a.	x	x	x	x	n.a.	x	x	x	x	x	x	x	n.a.	x	x	x
.						x	n.a.					x	x	x	x	n.a.	x	x	x	x	x		x					p	x	x	x	n.a.		x	x	x	n.a.		x	x	x	x	x	p	n.a.		p	p
	x					x		x	x	x	x	x	x	x	x	n.a.	x	x	x		x		p					p	p	p	p	n.a.		p	p	p	n.a.		p	p	p	p	p	p	n.a.			
																					x		p																									

EOT																												FU 01					FU 02								FU 03					FU 04						
EOTSG	EOTCb	EOTCis	EOTCap	EOTP	TREAT_Endo_EOT	TREAT_CDK46_EOT	PhyEx_EOT	Hema_EOT	BioChemistry_EOT	LabOther_EOT	CM_YN_EOT	AE01_EOT	AE02_EOT	BioM_EOT	BioMStool_EOT	FACTB_EOT	FACTCF_EOT	EQ5D5L_EOT	EOO_SOFU	CM	TROP2	BRCAResult	RF	BioM_Rel	DRF	Withdrawal	ReConsent	FU_PatStatus_01	FU_ACT_01	FU_EndoTreat_01	FU_CDK46Treat_01	FU_OtherExam_01	FU_PatStatus_02	FU_ACT_02	FU_EndoTreat_02	FU_CDK46Treat_02	FU_OtherExam_02	FACTB_FU02	FACTCF_FU02	EQ5D5L_FU02	FU_PatStatus_03	FU_ACT_03	FU_EndoTreat_03	FU_CDK46Treat_03	FU_OtherExam_03	FU_PatStatus_04	FU_ACT_04	FU_EndoTreat_04	FU_CDK46Treat_04	FU_OtherExam_04	FACTB_FU04	FACTCF_FU04
xMS					D		sD	D	sD	D	D	xMS	xMS	D	n.a.	D	D	D		D		D					p110	D	D	D	n.a.	D	D	D	D	n.a.	D	D	D	D	D	D	D	n.a.	D	D	D	p34	n.a.		D	D
					D	n.a.					D	D	D	D	n.a.	D	D	D	D	D		D					p99	D	D	D	n.a.		D	D	D	n.a.		D	D	D	D	D	p30	n.a.		p17	p17	p17	n.a.		p17	p17
DS					xM		xM	xM	xM	xM	D	D	D	xM	n.a.	xM	xM	xM		D		p42					p69	p31	p31	p31	n.a.		p18	p18	p18	n.a.		p18	p18	p18	p5	p5	p5	n.a.								
			sD		n.a.		sD	D	sD	D	D	sD	sD	D	n.a.	D	D	D		n.a.		n.a.	sD	D	sD		D	D	D	n.a.	n.a.		n.a.	n.a.	n.a.	n.a.		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.		n.a.	n.a.	n.a.	n.a.		n.a.	n.a.
																				D		p14																														

Doku-Reports

No	Phase	CRF	Pending since x weeks [if =0 then CRF just got pending OR pending time is undefined!]
	ReConsent	ReConsent	110
	Follow Up	FU_EndoTreat_04	34
	Follow Up	FU_PatStatus_05	21
	Follow Up	FU_ACT_05	21
	Follow Up	FU_EndoTreat_05	21
	Follow Up	FU_PatStatus_06	8
	Follow Up	FU_ACT_06	8
	Follow Up	FU_EndoTreat_06	8
	ReConsent	ReConsent	99
	Follow Up	FU_EndoTreat_03	30
	Follow Up	FU_PatStatus_04	17
	Follow Up	FU_ACT_04	17
	Follow Up	FU_EndoTreat_04	17
	Follow Up	FACTB_FU04	17
	Follow Up	FACTCF_FU04	17
	Follow Up	EQ5D5L_FU04	17
	Follow Up	FU_PatStatus_05	4
	Follow Up	FU_ACT_05	4
	Follow Up	FU_EndoTreat_05	4
	BRCAResult	BRCAResult	42
	ReConsent	ReConsent	69
	Follow Up	FU_PatStatus_01	31
	Follow Up	FU_ACT_01	31
	Follow Up	FU_EndoTreat_01	31
	Follow Up	FU_PatStatus_02	18
	Follow Up	FU_ACT_02	18
	Follow Up	FU_EndoTreat_02	18
	Follow Up	FACTB_FU02	18
	Follow Up	FACTCF_FU02	18

Doku-Reports

- Nutzen Sie die Listen?
- Welche Übersicht ist für Sie praktikabler?

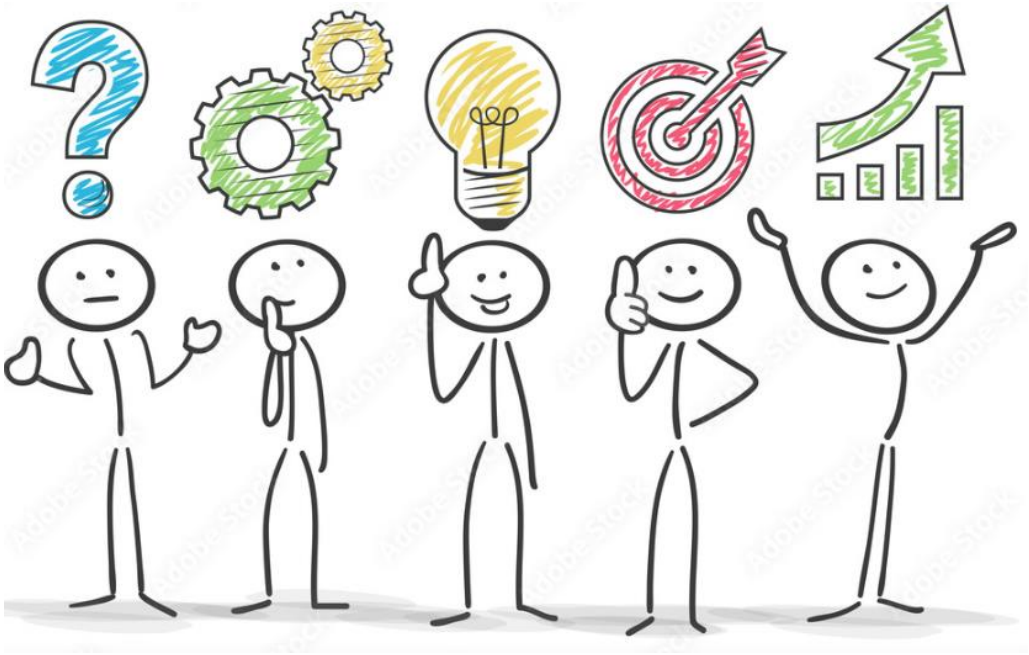
Doku-Reports - GFU

- GFU Daten GX und Insema gerade im Fokus
- Penelope auch wichtig – offenes noch dokumentieren
- Wir betrachten ein FU, dass älter als ein Jahr ist, als „nicht aktuell“.
- DCFs bitte beantworten

Pat Nr	Pat Status	Datum Rando	Letztes FU Zentrum	Letztes FU Event	Letztes FU PSA	Letztes Event PSA	Pat in PSA	In PSA seit	PSA Datenweitergabe	FU aktuell	Monate seit Kontakt	Datum WoC PSA	WoC Studie	Datum WoC Studie	Datum Lost2FU
117	A	4.7.2017	06.05.2020		11.05.2022		ja	26.06.2017	ja	nein	14		nein		
140	A	11.8.2017	06.05.2020		18.05.2022		ja+withdr.	03.08.2017	ja	nein	14	27.10.2022	nein		
256	A	10.11.2017					nein			nein	68		nein		
618	A	7.6.2018	04.05.2022				ja	24.05.2018	ja	nein	14		nein		

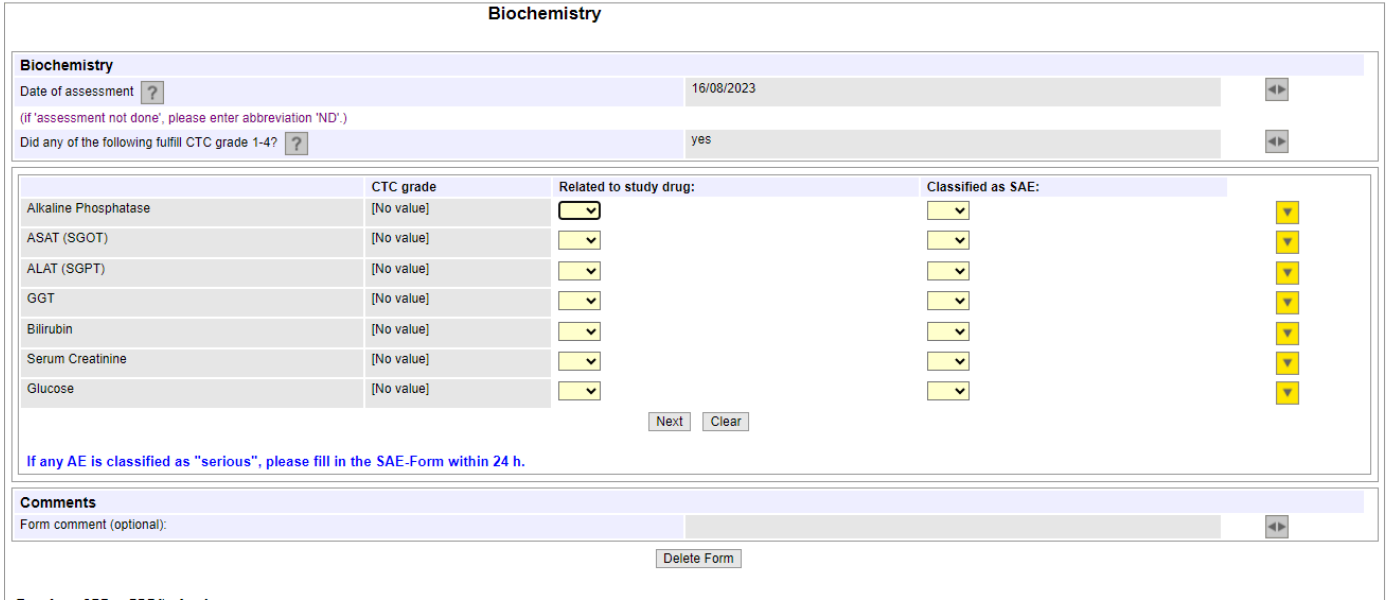
MARVIN

Eine Herausforderung für uns alle



MARVIN – Queries / Vetos / Messages

- Aktueller Review der automatischen Queries um zu verbessern (z.B. Biochmistry)



Biochemistry

Biochemistry

Date of assessment ?	16/08/2023
(if 'assessment not done', please enter abbreviation 'ND'.)	
Did any of the following fulfill CTC grade 1-4? ?	yes

	CTC grade	Related to study drug:	Classified as SAE:
Alkaline Phosphatase	[No value]		
ASAT (SGOT)	[No value]		
ALAT (SGPT)	[No value]		
GGT	[No value]		
Bilirubin	[No value]		
Serum Creatinine	[No value]		
Glucose	[No value]		

Next Clear

If any AE is classified as "serious", please fill in the SAE-Form within 24 h.

Comments

Form comment (optional):

Delete Form

Queries lösen

SASCIA Demo

dm_Investigator | 9991 GBG Training

SASCIA

Info / Help
Patients
Queries/Memos
Reports
Users
Centers
IWRS Materials

TEST INSTANCE

Queries
Overview

All/Open

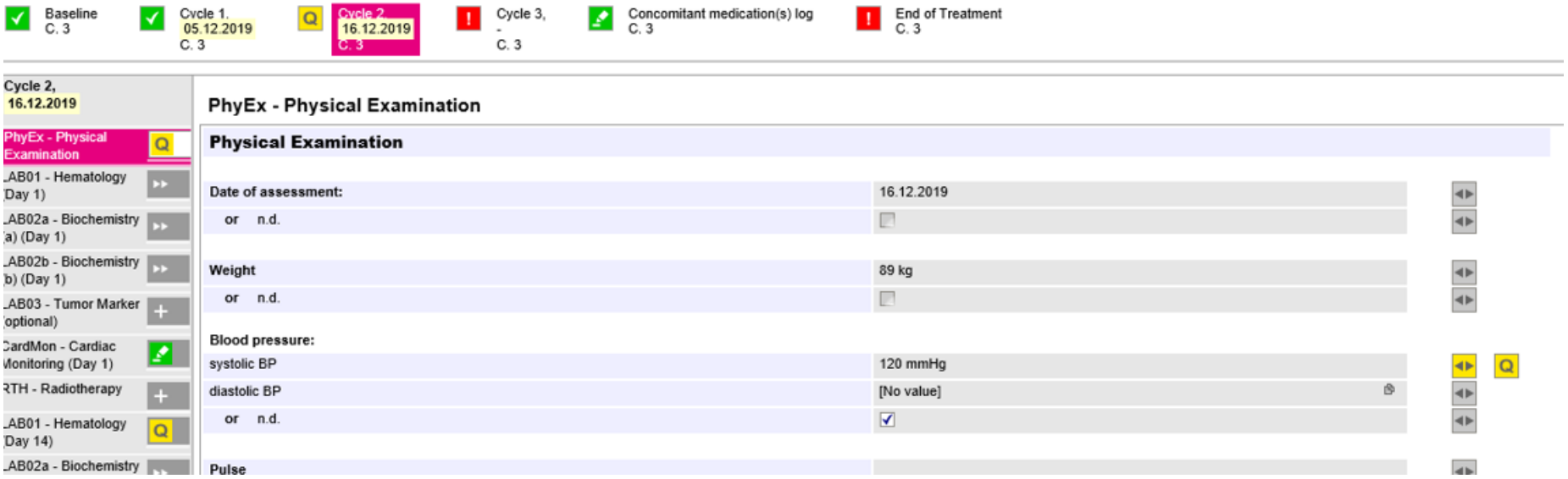
Flagfilter

Page 1 2 3 4 [Show all entries]

Type/Status	Note ID	Patient ID	Center	Center Affix	Event Name	Form Name	Concerning	Date	Author		+ / -
Q	115	0004	9991 GBG Training	9991	Baseline	BL - Central Pathology Surgical Tissue (breast)	If HER2 stauts assessment has been done, this field should not be empty. Please check.	28/09/2020	System	Show	
Q	116	0004	9991 GBG Training	9991	Baseline	BL - Central Pathology Surgical Tissue (lymph node)	This field is required, if FISH/CISH/SISH is positive or negative.	28/09/2020	System	Show	
Q	117	0004	9991 GBG Training	9991	Baseline	BL - Central Pathology Surgical Tissue (lymph node)	This field is required, if FISH/CISH/SISH is positive or negative.	28/09/2020	System	Show	
Q	118	0004	9991 GBG Training	9991	Baseline	BL - Central Pathology Surgical Tissue (lymph node)	If HER2 stauts assessment has been done, this field should not be empty. Please check.	28/09/2020	System	Show	
Q	123	0006	9991 GBG Training	9991	Baseline	BL - Biopsy before NACT	SNB is performed, but number of nodes not documented, please check.	01/10/2020	System	Edit	
Q	134	0013	9991 GBG Training	9991	Baseline	BL - Surgery	Please provide ER %, ER Stage is documented.	01/12/2020	System	Edit	
Q	135	0013	9991 GBG Training	9991	Baseline	BL - Surgery	Please provide PR %, PR Stage is documented.	01/12/2020	System	Edit	
Q	138	0006	9991 GBG Training	9991	Baseline	BL - Surgery	Please check if tumor size could be provided	02/12/2020	System	Edit	
Q	140	0008	9991 GBG Training	9991	Baseline	BL - Biopsy before NACT	Please check central pathology HER2 status, positive patients could not be included in the study.	08/12/2020	System	Edit	
Q	147	0010	9991 GBG Training	9991	Baseline	BL - Adjuvant Radiotherapy V4	If patient has received radiation therapy, please provide start and end date and whether the listed areas were radiated or not.	14/01/2021	System	Edit	
Q	150	0032	9991 GBG Training	9991	Baseline	BL - Imaging (at primary diagnosis)	please completed	17/01/2021	mon_Monitor2	Edit	

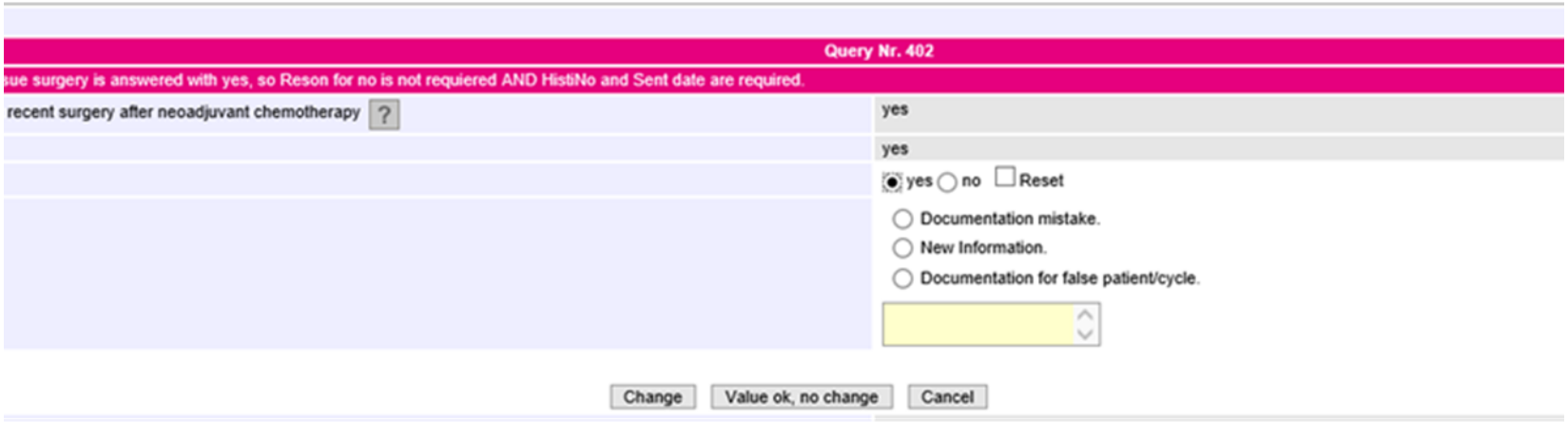
Querylist

Queries lösen



Queryansicht im CRF

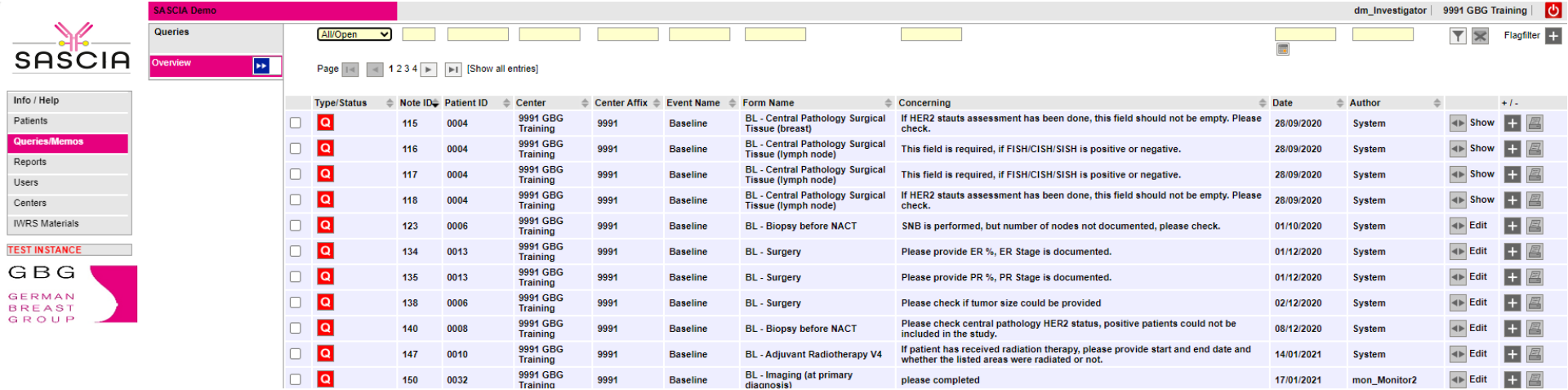
Queries lösen



Queryansicht

Queryansicht – auf CRFs mit nur Leserechten

Queries lösen



Back to Querylist

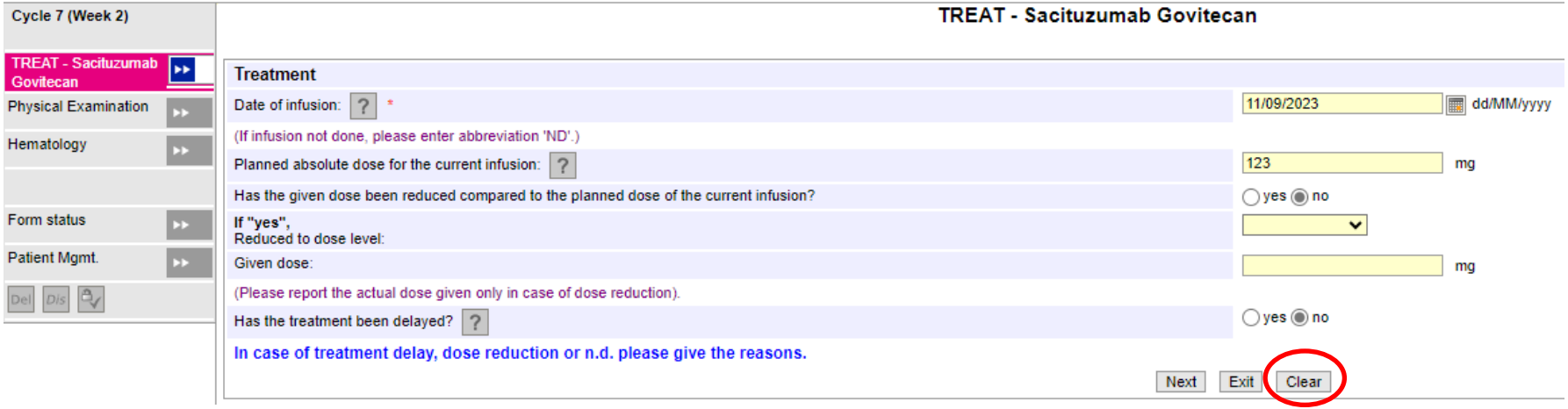
Daten Korrekturen ohne Query

- **Baseline Event**
  - solange nicht signiert und nicht randomisiert

- **nicht Baseline Events**
  - so lange nicht signiert bzw. von Monitor monitoriert und gelockt

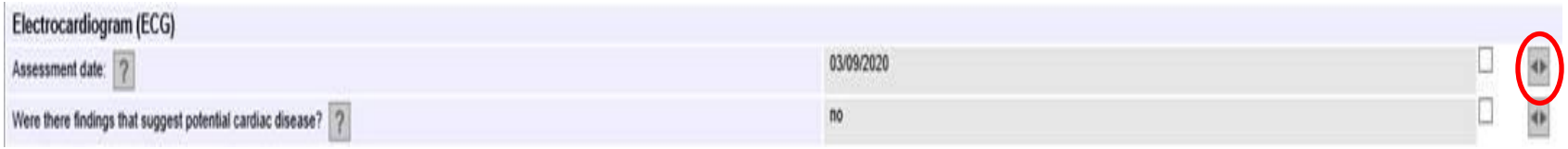
Items korrigieren vor Save

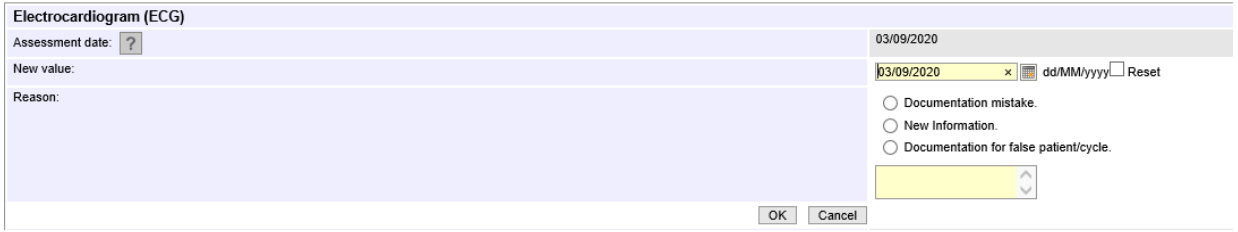
- *Clear button*



Items korrigieren nach Save

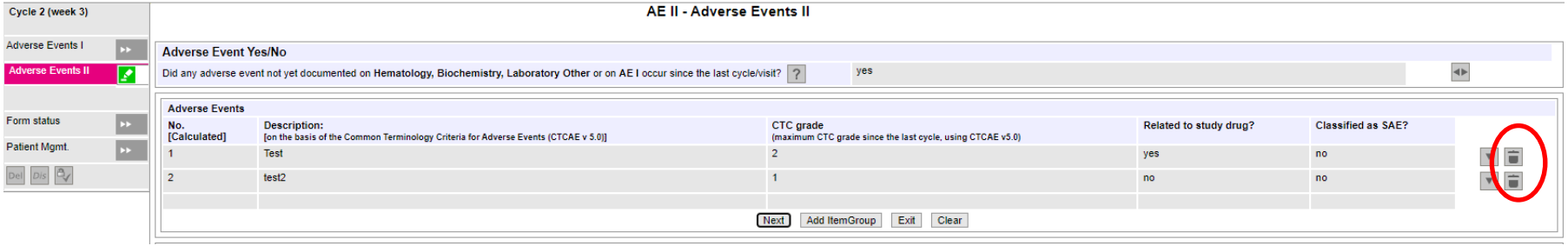
- ***Edit*** **icon** 

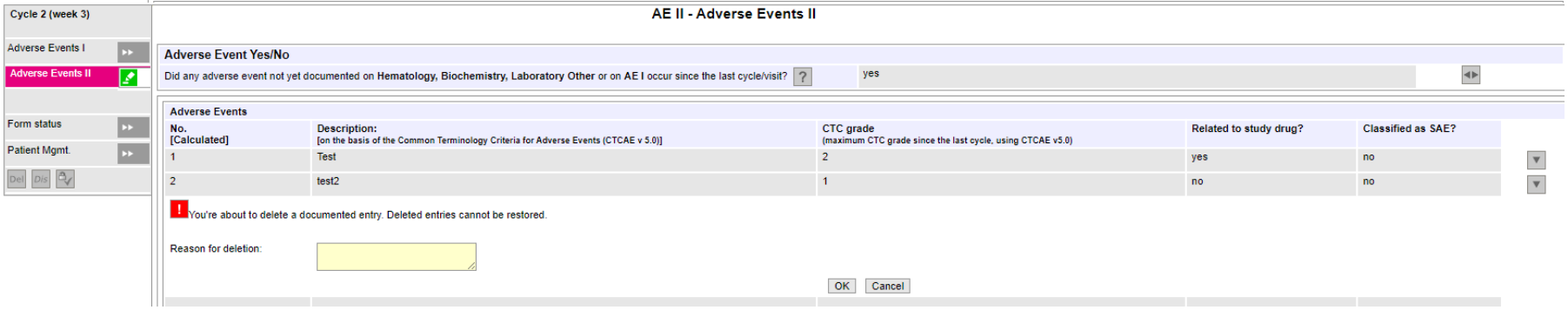




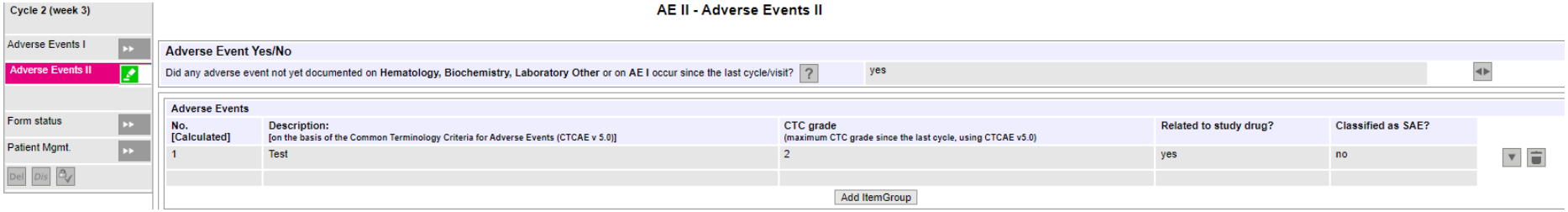
Item groups löschen nach Save

- *Delete* icon  für repeating item groups

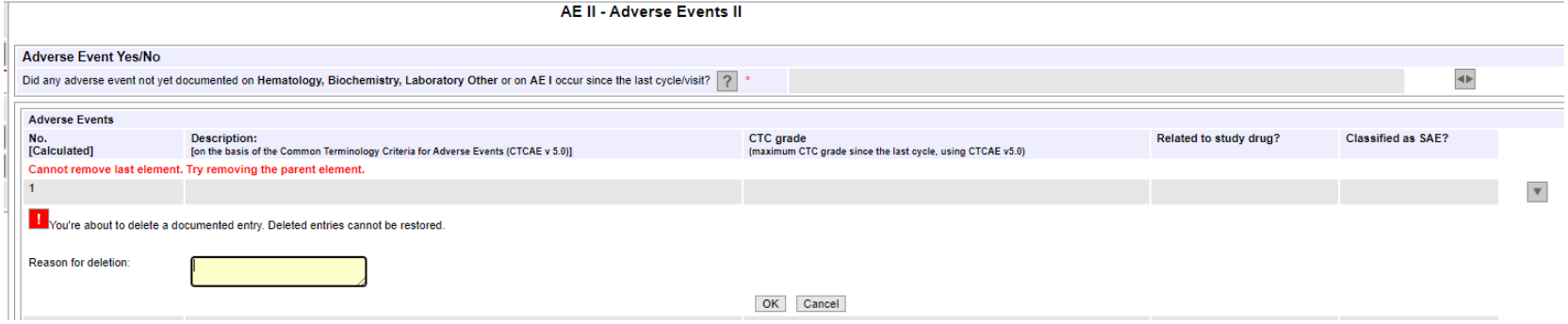




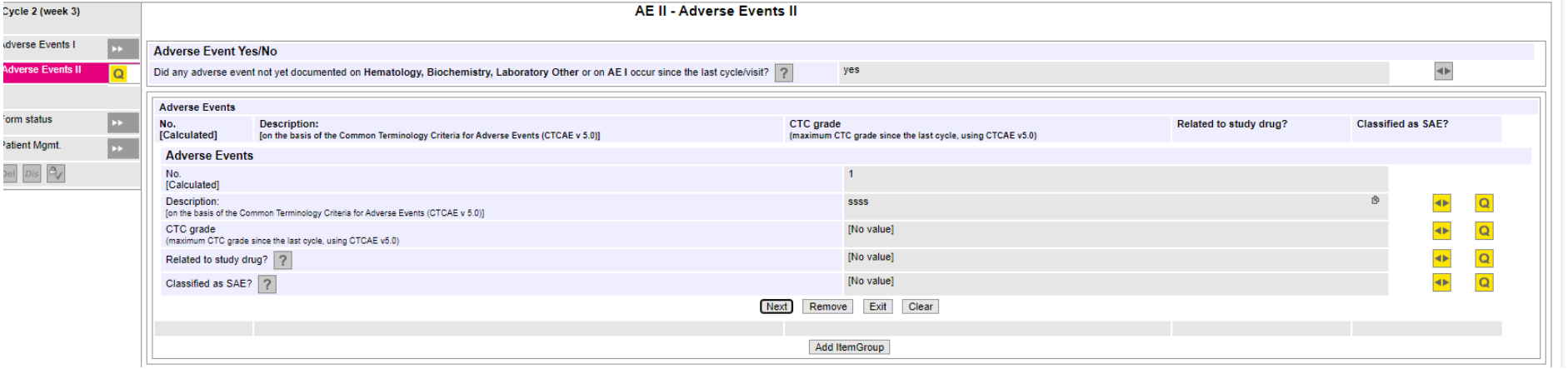
Item groups löschen nach Save



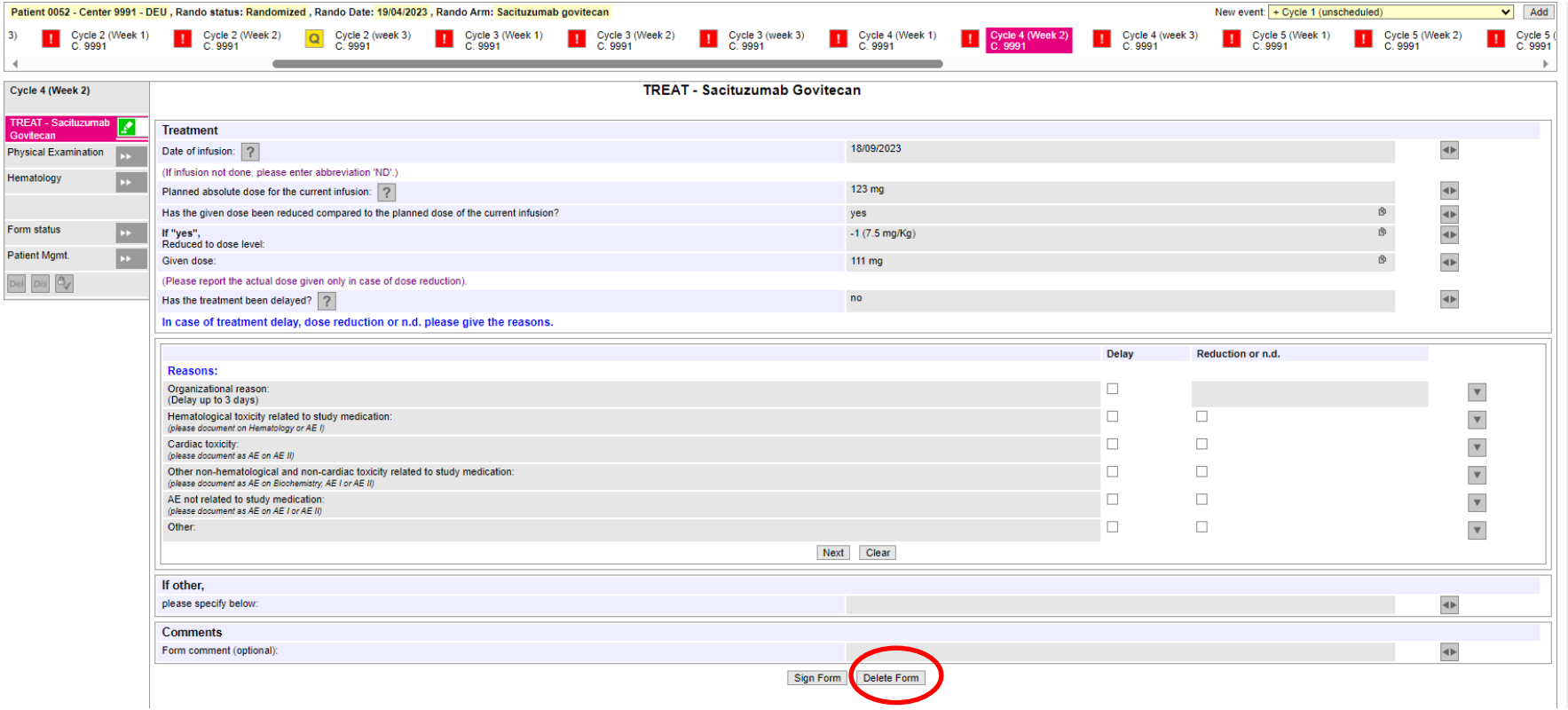
Löschen von leeren Zeilen, wenn es sonst keine Einträge gibt – geht nicht



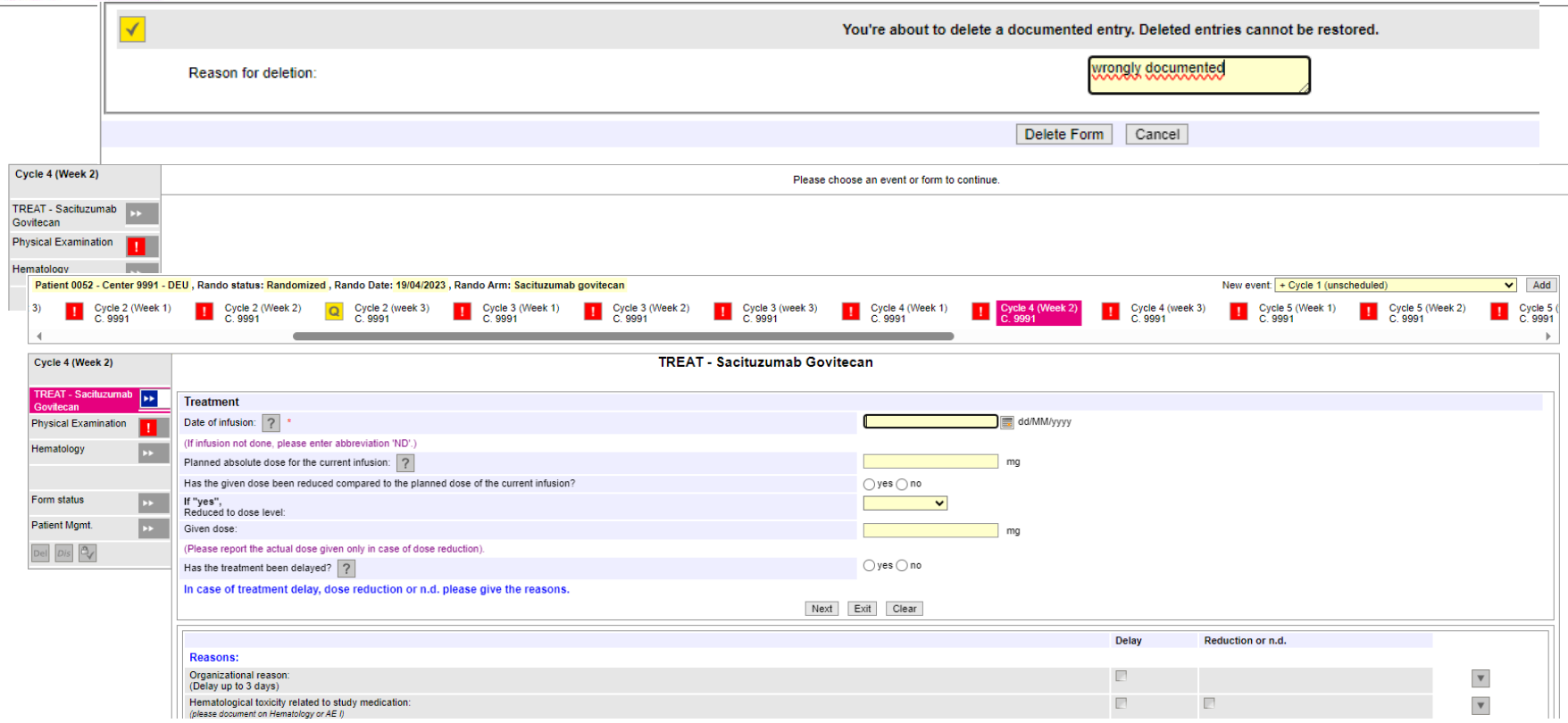
Item groups löschen nach Save



Form löschen nach Save

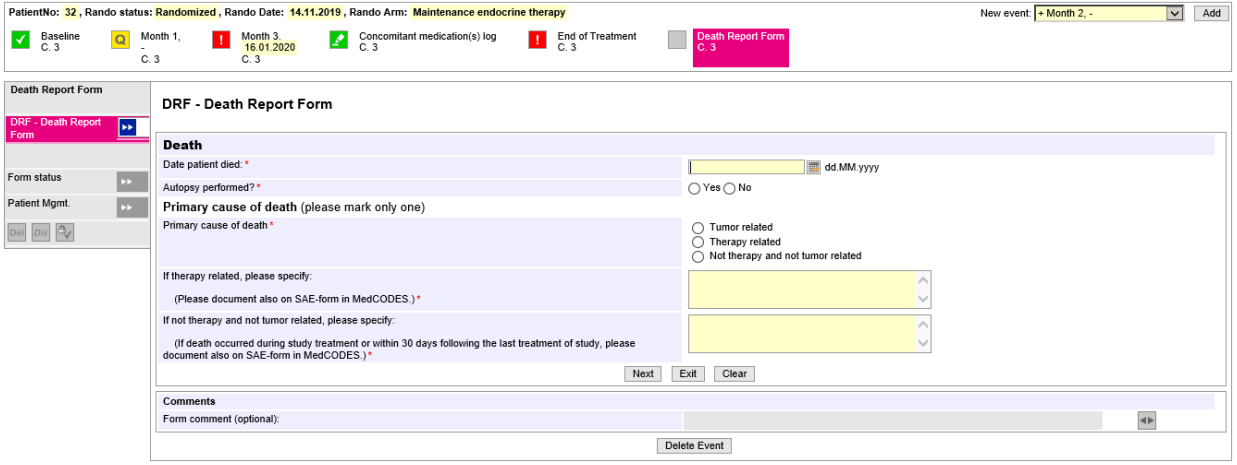


Form löschen nach Save



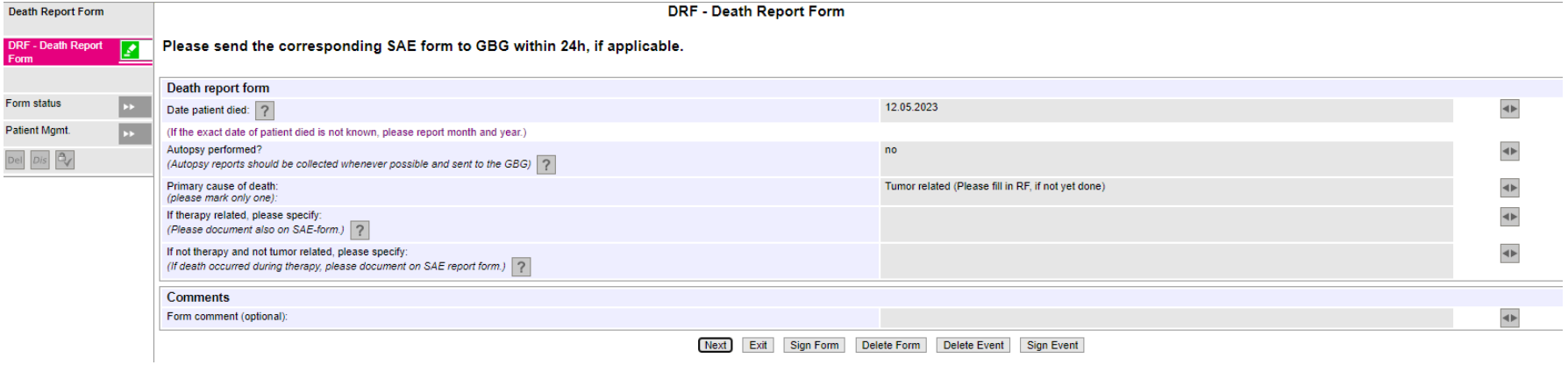
Event Löschen vor Save

- Versehentlich angelegte Events über das New Event DropDown – können vor Dateneingabe mit *Delete Event* button gelöscht werden



Event Löschen nach Save

- möglich für DRF, unscheduled Events



Adverse Events

pain in legs + light ant-walking in fingertips neurogical

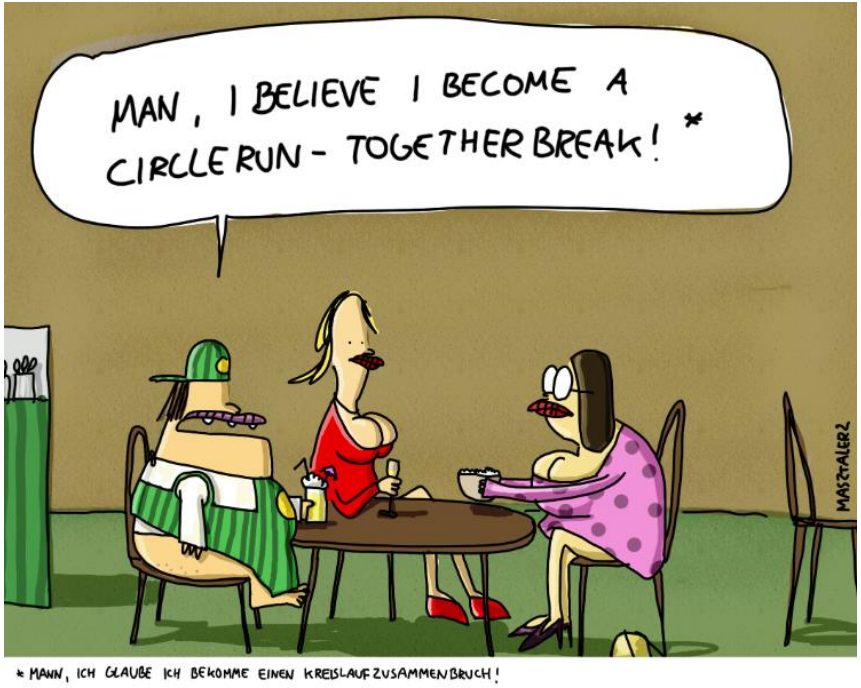
eye songs twitching

Open mouth

gripal infect

2. Adverse event	1	2	3	4
Description (on the basis of CTCAE v3.0):	○	X	○	○

deafness both feeds



* MANN, ICH GLAUBE ICH BEKOMME EINEN KREISLAUFZUSAMMENBRUCH!

DRAWING PAIN IN THE RIGHT BREAST

modified Itemafter astrazeneca- vaccination one day: chills, joint and limb pain

AEs in den Puplikationen

Table 2. Safety

Adverse events *N* (%)	Durvalumab *N* = 92[c]		Placebo *N* = 82		*P*-value any grade	*P*-value grade 3–4
	Any grade	Grade 3–4	Any grade	Grade 3–4		
Anaemia	87 (94.6)	2 (2.2)	79 (96.3)	2 (2.4)	0.724	1.000
Leukopenia	81 (88.0)	30 (32.6)	79 (96.3)	30 (36.6)	0.053	0.633
Neutropenia	71 (77.2)	34 (37.0)	67 (81.7)	34 (41.5)	0.574	0.641
Febrile neutropenia		4 (4.3)		2 (2.4)		0.685
Thrombopenia	35 (38.0)	1 (1.1)	28 (34.1)	2 (2.4)	0.637	0.602
Increased bilirubin	5 (5.4)	0 (0.0)	6 (7.3)	0 (0.0)	0.758	n.a.
Increased AP	43 (46.7)	0 (0.0)	40 (48.8)	0 (0.0)	0.879	n.a.
Increased ASAT	45 (48.9)	3 (3.3)	28 (34.1)	0 (0.0)	0.065	0.248
Increased ALAT	53 (57.6)	4 (4.3)	45 (54.9)	3 (3.7)	0.761	1.000
Increased creatinine	10 (10.9)	0 (0.0)	7 (8.5)	0 (0.0)	0.799	n.a.
Hyperglycaemia	32 (38.6)	0 (0.0)	37 (51.4)	0 (0.0)	0.145	n.a.
Fatigue	70 (76.1)	5 (5.4)	68 (82.9)	9 (11.0)	0.349	0.264
Headache	38 (41.3)	1 (1.1)	28 (34.1)	0 (0.0)	0.352	1.000
Vertigo	24 (26.1)	0 (0.0)	22 (26.8)	0 (0.0)	1.000	n.a.
Hypotension	3 (3.3)	0 (0.0)	6 (7.3)	0 (0.0)	0.310	n.a.
Alopecia	85 (92.4)	–	78 (95.1)	–	0.543	–
Nausea	54 (58.7)	0 (0.0)	53 (64.6)	7 (8.5)	0.439	0.004
Anorexia	20 (21.7)	1 (1.1)	19 (23.2)	1 (1.2)	0.857	1.000
Vomiting	12 (13.0)	1 (1.1)	11 (13.4)	1 (1.2)	1.000	1.000
Diarrhoea	26 (28.3)	3 (3.3)	34 (41.5)	0 (0.0)	0.080	0.248
Constipation	29 (31.5)	1 (1.1)	34 (41.5)	1 (1.2)	0.207	1.000
Mucositis	32 (34.8)	2 (2.2)	33 (40.2)	0 (0.0)	0.531	0.499
Stomatitis	15 (16.3)	2 (2.2)	14 (17.1)	0 (0.0)	1.000	0.499
Skin reactions	45 (48.9)	2 (2.2)	39 (47.6)	1 (1.2)	0.880	1.000
Hand–foot-syndrome	11 (12.0)	1 (1.1)	16 (19.5)	3 (3.7)	0.210	0.344
Peripheral sensory neuropathy	76 (82.6)	9 (9.8)	69 (84.1)	9 (11.0)	0.840	0.809

Loibl S, et al. Ann Oncol. 2019

AEs in den Puplikationen

Table 3. Adverse Events during the Neoadjuvant Phase at the Second Interim Analysis.*

Event	Pembrolizumab–Chemotherapy (N=781)		Placebo–Chemotherapy (N=389)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
	number of patients (percent)			
Any adverse event	777 (99.5)	633 (81.0)	389 (100.0)	295 (75.8)
Treatment-related adverse event†	773 (99.0)	600 (76.8)	388 (99.7)	281 (72.2)
Nausea	490 (62.7)	26 (3.3)	246 (63.2)	5 (1.3)
Alopecia	471 (60.3)	14 (1.8)	220 (56.6)	8 (2.1)
Anemia	430 (55.1)	142 (18.2)	215 (55.3)	58 (14.9)
Neutropenia	365 (46.7)	270 (34.6)	183 (47.0)	129 (33.2)
Fatigue	321 (41.1)	27 (3.5)	147 (37.8)	6 (1.5)
Diarrhea	230 (29.4)	17 (2.2)	92 (23.7)	5 (1.3)
Elevated alanine aminotransferase level	199 (25.5)	41 (5.2)	96 (24.7)	9 (2.3)
Vomiting	199 (25.5)	18 (2.3)	85 (21.9)	6 (1.5)
Asthenia	191 (24.5)	25 (3.2)	99 (25.4)	9 (2.3)
Constipation	185 (23.7)	0	82 (21.1)	0
Decreased neutrophil count	185 (23.7)	146 (18.7)	112 (28.8)	90 (23.1)
Rash	170 (21.8)	7 (0.9)	59 (15.2)	1 (0.3)
Peripheral neuropathy	154 (19.7)	15 (1.9)	82 (21.1)	4 (1.0)
Adverse event of interest‡	304 (38.9)	101 (12.9)	71 (18.3)	7 (1.8)
Infusion reaction	132 (16.9)	20 (2.6)	43 (11.1)	4 (1.0)
Hypothyroidism	107 (13.7)	3 (0.4)	13 (3.3)	0
Hyperthyroidism	36 (4.6)	2 (0.3)	4 (1.0)	0
Severe skin reaction	34 (4.4)	30 (3.8)	4 (1.0)	1 (0.3)
Adrenal insufficiency	18 (2.3)	10 (1.3)	0	0

Schmid P et all N Engl J Med. 2020

AE Coding

Was steht in der Akte?

- im besten Fall Formblätter Terms mit den gängigen Nebenwirkungen der Studie (deutsch)
- Freitext könnte Probleme mit sich bringen
- ungünstige Überstzungen
- Patientin klagt über Kopfschmerzen und ziehen im Rücken
- Schwindel
- Schmerzen
- Arthalgia / Myalgia

→ Orientierung an den CTC AE Kriterien

https://www.gbg.de/de/rechner/ctcae.php Common Terminology Criteria for Adverse Events (CTCAE) - GBG

AE Coding

- Verbatim = wörtlich / wortgetreu → was in Akte steht
- wird zu MedDRA Term kodiert
- Medical Dictionary for Regulatory Activities

System, Organ, Class	SOC	Represents anatomical or physiological system, etiology, or purpose
High Level Group Term	HLGT	Links for HLTs
High Level Term	HLT	Groups based upon anatomy, pathology, physiology, etiology or function
Preferred Term	PT	Single medical concept for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure and medical social or family history characteristics
Lowest Level Term	LLT	How information is communicated; how observation might be reported in practice

AE Coding

Term Details in Primary Language

PT - Preferred Term

MedDRA Code	MedDRA Term
10013573	Schwindelgefuehl

SOC Code	SOC Name	Primary SOC
10029205	Erkrankungen des Nervensystems	Y
10047065	Gefaesserkrankungen	N
10007541	Herzerkrankungen	N

SMQ Code	SMQ Name	Scope	Status	Category	Weight	Addition Version	Last Modified Version
20000048	Anticholinerges Syndrom (SMQ)	Broad	Active	B	0	9.1	9.1
20000172	Vestibulaere Stoerungen (SMQ)	Broad	Active	A	0	12.0	12.0

Definition acc. CTC AE: A disorder characterized by a disturbing sensation of lightheadedness, unsteadiness, giddiness, spinning or rocking.

PT Occurrences in MedDRA

- PT **Schwindelgefuehl**
  - HLT Neurologische klinische Zeichen und Symptome ANE
    - HLGT Neurologische Erkrankungen ANE
      - SOC Erkrankungen des Nervensystems
- PT **Schwindelgefuehl**
  - HLT Kreislaufkollaps und Schock
    - HLGT Erkrankungen und Schock durch erniedrigten und unspezifischen Blutdruck
      - SOC Gefaesserkrankungen
- PT **Schwindelgefuehl**
  - HLT Klinische Zeichen und Symptome des Herzens ANE
    - HLGT Klinische Zeichen und Symptome bei Herzerkrankungen ANE
      - SOC Herzerkrankungen

PT Occurrences in SMQ

- PT B Schwindelgefuehl
  - SMQ Anticholinerges Syndrom (SMQ)
- PT Schwindelgefuehl
  - SMQ Vestibulaere Stoerungen (SMQ)
    - SMQ Hoerstoerungen und vestibulaere Stoerungen (SMQ)

AE Coding

Term Details in Primary Language

PT - Preferred Term

MedDRA Code	MedDRA Term
10047340	Vertigo

SOC Code	SOC Name	Primary SOC
10013993	Erkrankungen des Ohrs und des Labyrinths	Y
10029205	Erkrankungen des Nervensystems	N

SMQ Code	SMQ Name	Scope	Status	Category	Weight	Addition Version	Last Modified Version
20000172	Vestibulaere Stoerungen (SMQ)	Narrow	Active	A	0	12.0	12.0

PT Occurrences in MedDRA

- PT **Vertigo**
  - HLT Klinische Zeichen und Symptome des Innenohrs
    - HLGT Erkrankungen des Innenohrs und des VIII. Hirnnervs
      - SOC Erkrankungen des Ohrs und des Labyrinths
- PT **Vertigo**
  - HLT Schwindel ANE
    - HLGT Neurologische Erkrankungen ANE
      - SOC Erkrankungen des Nervensystems

PT Occurrences in SMQ

- PT Vertigo
  - SMQ Vestibulaere Stoerungen (SMQ)
    - SMQ Hoerstoerungen und vestibulaere Stoerungen (SMQ)

Definition: A disorder characterized by a sensation as if the external world were revolving around the patient (objective vertigo) or as if he himself were revolving in space (subjective vertigo).

AE Coding

- **Myalgia**

Definition: A disorder characterized by marked discomfort sensation originating from a muscle or group of muscles.

- **Arthralgia**

Definition: A disorder characterized by a sensation of marked discomfort in a joint.

AE Coding

- **V.A. Polyp**
  - Please query- More information is needed to code the verbatim. Could you please specify what does V.A mean. Is it Vaginal or something else? Thank you.
- **SODA BURNING**
  - Please query - could you please specify the kind and location of the burning? Thank you

Verbatim	LLT/Drug Name	PT/ATC1	HLT/ATC2	HLGT/ATC3	SOC/ATC4	Status in ID-Code	Follow-up actions for term not found or coding submitted rejected
MOTOR DISABILITY EYELID	Motor dysfunction	Motor dysfunction	Dyskinesias and movement disorders NEC	Movement disorders (incl parkinsonism)	Nervous system disorders	Rejected	Please query- More information is needed to code this AE. Could you please clarify the AE? Thank you.
MOTOR DISABILITY EYELID	Oculomotor nerve disorder	IIIrd nerve disorder	Eye movement disorders	Cranial nerve disorders (excl neoplasms)	Nervous system disorders	Rejected	Please query- More information is needed to code this AE. Could you please clarify the AE? Thank you.

AE Coding

Verbatim	LLT/Drug Name	PT/ATC1	HLT/ATC2	HLGT/ATC 3	SOC/ATC4	Status in ID-Code	Follow-up actions for term not found or coding submitted rejected
FREEZING	Freezing phenomenon	Freezing phenomenon	Parkinson's disease and parkinsonism	Movement disorders (incl parkinsonism)	Nervous system disorders	Rejected	Please query - Too vague for coding. Specify this term and what this refers to. Is it freezing phenomenon? Other?
THORACIC PRESSING FEELING	Chest pressure sensation	Chest discomfort	Pain and discomfort NEC	General system disorders NEC	General disorders and administration site conditions	Rejected	Please query- Priya comment 'need to confirm does this term refer to back pain or noncardiac chest pain'
FEELING OF FULLNESS						Not found	Please query - the verbatim is too vague for coding. Please specify type and location of the fullness feeling.

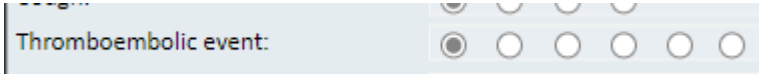
AE Coding

Meningoencephalitis: ○ ♂ ♂ ♂ ♂ ♂

Reported Term for the Adverse Event	GBG Verbatim on SAE
MENINGOENCEPHALITIS	meningoencephalitis, viral, without pathogen detection

- LLT Meningococcal encephalitis
- LLT Meningoencephalitis
- LLT Meningoencephalitis adenoviral
- LLT Meningoencephalitis amebic
- LLT Meningoencephalitis amoebic
- LLT Meningoencephalitis bacterial
- LLT Meningoencephalitis due to toxoplasmosis
- LLT Meningoencephalitis helminthic
- LLT Meningoencephalitis herpes simplex neonatal
- LLT Meningoencephalitis herpetic
- LLT Meningoencephalitis viral

AE Coding



Reported Term for the Adverse Event	GBG Verbatim on SAE
THROMBOEMBOLIC EVENT	central pulmonary embolism on both sides
	Subclavian vein thrombosis

AE Coding

PT Occurrences in MedDRA

- PT **Catheter site thrombosis**
  - HLT Implant and catheter site reactions
    - HLGT Administration site reactions
      - SOC General disorders and administration site conditions
- PT **Catheter site thrombosis**
  - HLT Implant and catheter site reactions
    - HLGT Administration site reactions
      - SOC Injury, poisoning and procedural complications
- PT **Catheter site thrombosis**
  - HLT Non-site specific embolism and thrombosis
    - HLGT Embolism and thrombosis
      - SOC Vascular disorders

PT Occurrences in MedDRA

- PT **Embolism**
  - HLT Non-site specific embolism and thrombosis
    - HLGT Embolism and thrombosis
      - SOC Vascular disorders

PT Occurrences in MedDRA

- PT **Subclavian vein thrombosis**
  - HLT Peripheral embolism and thrombosis
    - HLGT Embolism and thrombosis
      - SOC Vascular disorders

PT Occurrences in MedDRA

- PT **Thrombosis**
  - HLT Non-site specific embolism and thrombosis
    - HLGT Embolism and thrombosis
      - SOC Vascular disorders

PT Occurrences in MedDRA

- PT **Pulmonary thrombosis**
  - HLT Pulmonary thrombotic and embolic conditions
    - HLGT Pulmonary vascular disorders
      - SOC Respiratory, thoracic and mediastinal disorders
- PT **Pulmonary thrombosis**
  - HLT Pulmonary embolism and thrombosis
    - HLGT Embolism and thrombosis
      - SOC Vascular disorders

AE Coding

Auswirkungen der Dokumentation auf die Kodierung von AE-Daten

- **Eine angemessene Kodierung erfordert klare Ausgangsdaten**

  Mehrdeutige Informationen

  Krämpfe (Muskel, Menstruation, Bauch?)

  Schmerz (Schmerz wo?)

  Mehrdeutige Abkürzungen (MI (Myokardinfarkt oder ?,

  Verminderte BS (Atemgeräusche, Darmgeräusche oder Blutzucker?)

  Vage Informationen

  Der Patient fühlte sich "verschwommen“

  Unspezifische Informationen "Ödem am linken Handgelenk" versus "Ödem an der Injektionsstelle am linken Handgelenk"

GBG
GERMAN
BREAST
GROUP

HERZLICHEN DANK!