IT-gestützte Behandlung von Patienten

Erfahrungsbericht über die Zusammenarbeit mit Patienten, Ärzten, Unternehmen und Krankenhäusern

Univ. Doz. Dr. Gerhard Rumpold
Geschäftsführer, ESD OG

Alexander Wolf
Produktmanagement saratiba, World-Direct eBusiness solutions GmbH

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Center for Personalized Cancer Medicine

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ESD

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Center for Personalized Cancer Medicine

K1 COMET-Zentrum

Oncotyrol ist ein K1-Zentrum für personalisierte Krebsmedizin
im Rahmen des COMET Programms
der Österreichischen Forschungsförderungsgesellschaft FFG

COMET
Competence Centers for Excellent Technologies

FFG

bmvit
Bundesministerium für Verkehr, Innovation und Technologie

bmwfj
Bundesministerium für Wirtschaft, Familie und Jugend

Tirol
Standortagentur

Wirtschaft Land Salzburg

World-Direct eBusiness Solutions GmbH

100%ige A1 Telekom Austria Tochter

- 70 Mitarbeiter
- Hauptsitz: Sistrans, Innsbruck
- Einheiten in Wien, Linz
- > 700 Outsourcing-Projekte
- Primär Mittelständische und Großkunden
- Microsoft CRM Gold Partner

Geschäftstätigkeiten

- Technisches Consulting
- Entwicklung und Anpassung von webbasierten Applikationen
- Design und Bedienführung
- Technischer Betrieb

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Funktionale Ziele

- Klinisches Krebsregister
- Leitlinienbasierte Diagnostik und Therapie
- Automatisiertes Tumorboard
- PatientInnensicherheit
- Einheitliche Behandlung
- Zwischen einzelnen Kliniken vergleichbare und evtl. austauschbare klinische Informationen z.B. Survival, PatientInnenzufriedenheit

Nichtfunktionale Ziele

- Zertifizierung nach ISO 13485
- Usability
- Zielgruppe (im 1. Schritt) → Ärzte

Das Entwicklungsteam

- 4 Medical Doctors
- 10 IT Specialists
- 2 Ass. Prof. Medical Psychology
  3 IT Specialists
- 1 Project Manager

AUTONOME PROVINZ BOZEN – SÜDTIROL
PROVINCIA AUTONOMA DI BOLZANO – ALTO ADIGE
PROVINZIA AUTONOMA DE BULSAN – SUDTIROL
Südtiroler Sanitätsbetrieb
Azienda Sanitaria dell'Alto Adige
Azienda Sanitera de Sudtirol

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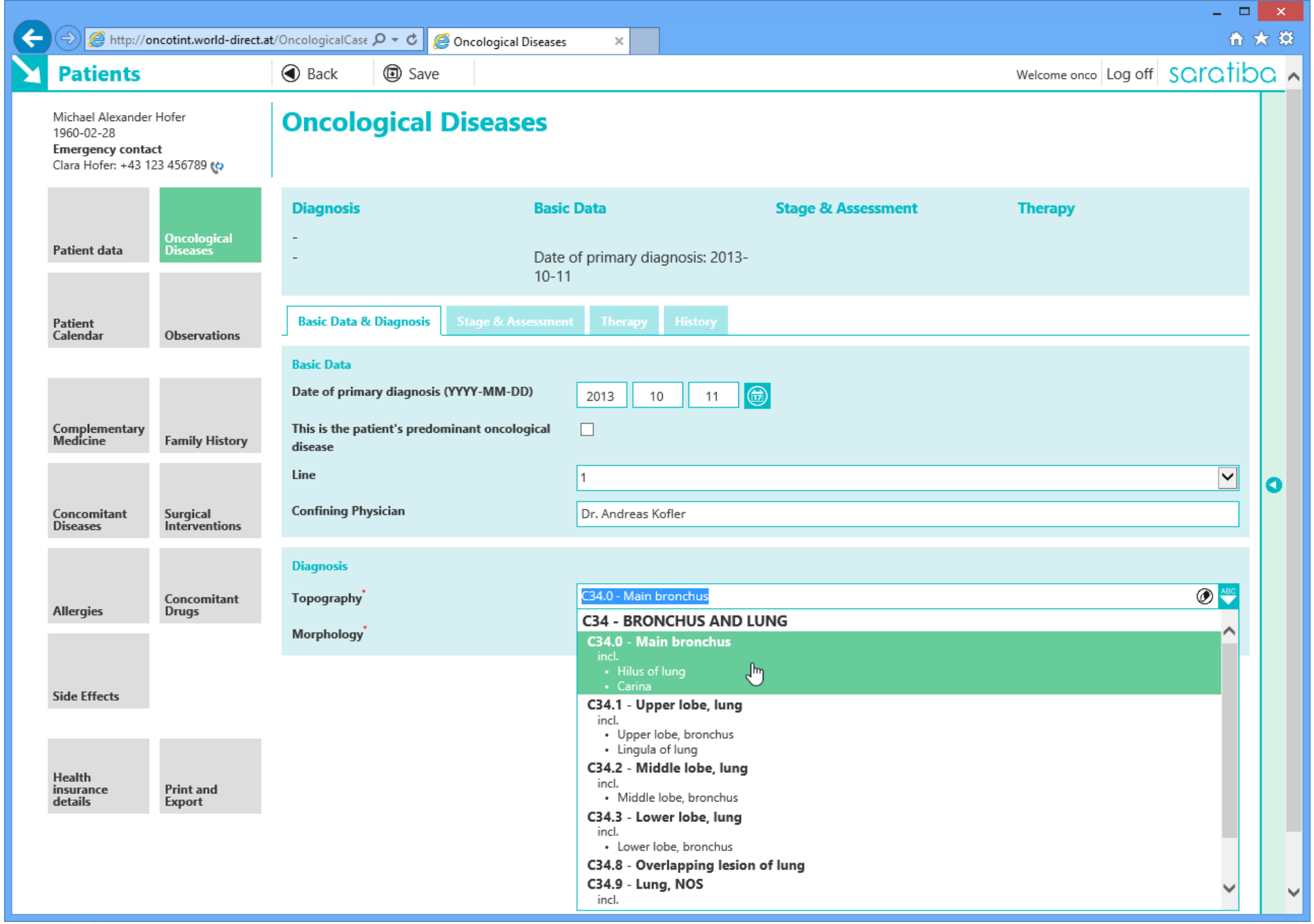
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Oncological Diseases
Patients
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saratiba
Michael Alexander Hofer
1960-02-28
Emergency contact
Clara Hofer: +43 123 456789
Oncological Diseases
Patient data
Oncological Diseases
Patient Calendar
Observations
Complementary Medicine
Family History
Concomitant Diseases
Surgical Interventions
Allergies
Concomitant Drugs
Side Effects
Health insurance details
Print and Export
Diagnosis
Basic Data
Stage & Assessment
Therapy
-
-
Date of primary diagnosis: 2013-10-11
Basic Data & Diagnosis
Stage & Assessment
Therapy
History
Basic Data
Date of primary diagnosis (YYYY-MM-DD)
2013
10
11
This is the patient's predominant oncological disease
Line
1
Confining Physician
Dr. Andreas Kofler
Diagnosis
Topography
Morphology
C34.0 - Main bronchus
C34 - BRONCHUS AND LUNG
C34.0 - Main bronchus
incl.
Hilus of lung
Carina
C34.1 - Upper lobe, lung
incl.
Upper lobe, bronchus
Lingula of lung
C34.2 - Middle lobe, lung
incl.
Middle lobe, bronchus
C34.3 - Lower lobe, lung
incl.
Lower lobe, bronchus
C34.8 - Overlapping lesion of lung
C34.9 - Lung, NOS
incl.

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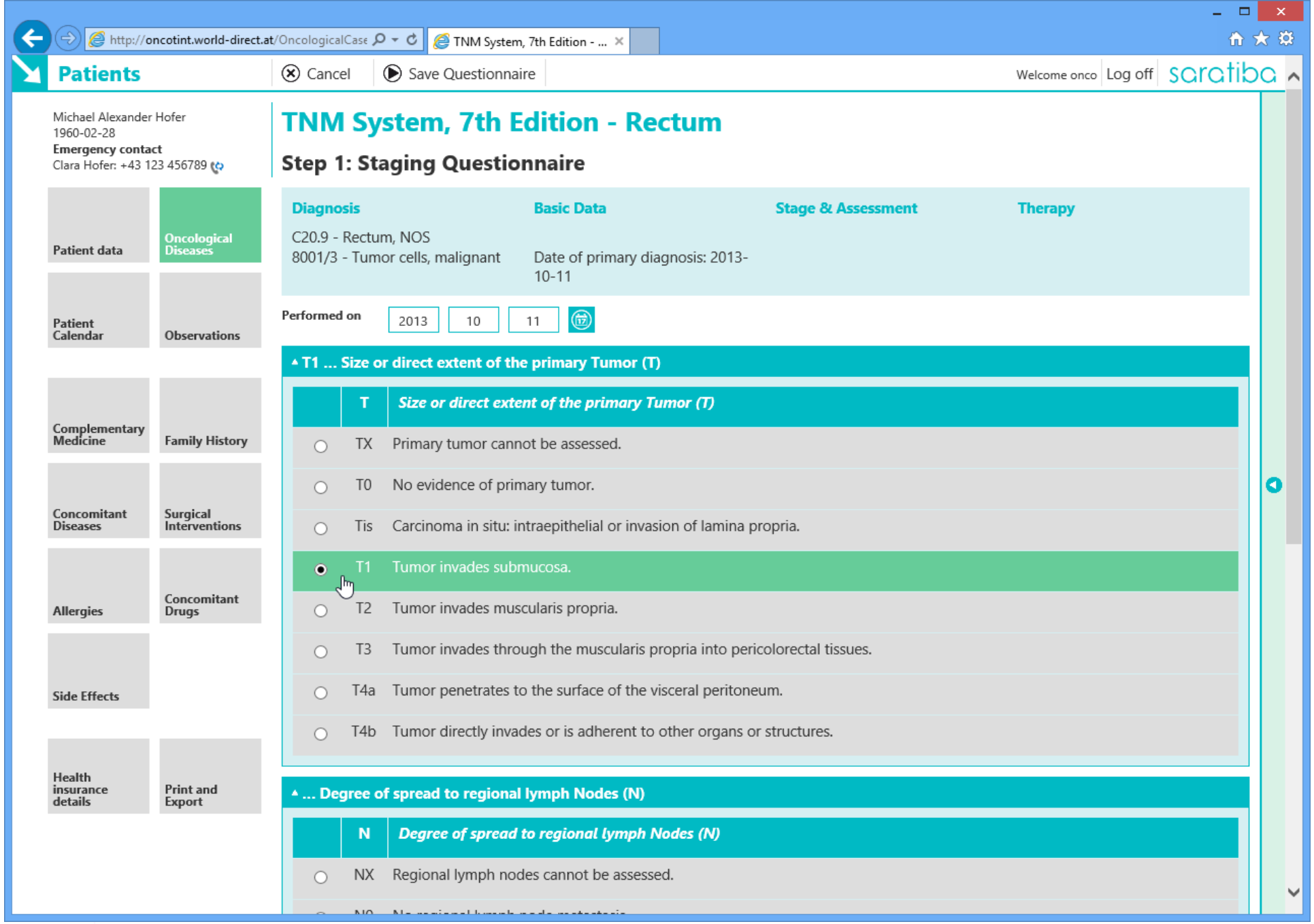
http://oncotint.world-direct.at/OncologicalCase
TNM System, 7th Edition - ...
Patients
Cancel
Save Questionnaire
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Log off
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Michael Alexander Hofer
1960-02-28
Emergency contact
Clara Hofer: +43 123 456789
TNM System, 7th Edition - Rectum
Step 1: Staging Questionnaire
Patient data
Oncological Diseases
Patient Calendar
Observations
Complementary Medicine
Family History
Concomitant Diseases
Surgical Interventions
Allergies
Concomitant Drugs
Side Effects
Health insurance details
Print and Export
Diagnosis
Basic Data
Stage & Assessment
Therapy
C20.9 - Rectum, NOS
8001/3 - Tumor cells, malignant
Date of primary diagnosis: 2013-10-11
Performed on
2013
10
11
T1 ... Size or direct extent of the primary Tumor (T)
T
Size or direct extent of the primary Tumor (T)
TX Primary tumor cannot be assessed.
T0 No evidence of primary tumor.
Tis Carcinoma in situ: intraepithelial or invasion of lamina propria.
T1 Tumor invades submucosa.
T2 Tumor invades muscularis propria.
T3 Tumor invades through the muscularis propria into pericolorectal tissues.
T4a Tumor penetrates to the surface of the visceral peritoneum.
T4b Tumor directly invades or is adherent to other organs or structures.
... Degree of spread to regional lymph Nodes (N)
N
Degree of spread to regional lymph Nodes (N)
NX Regional lymph nodes cannot be assessed.

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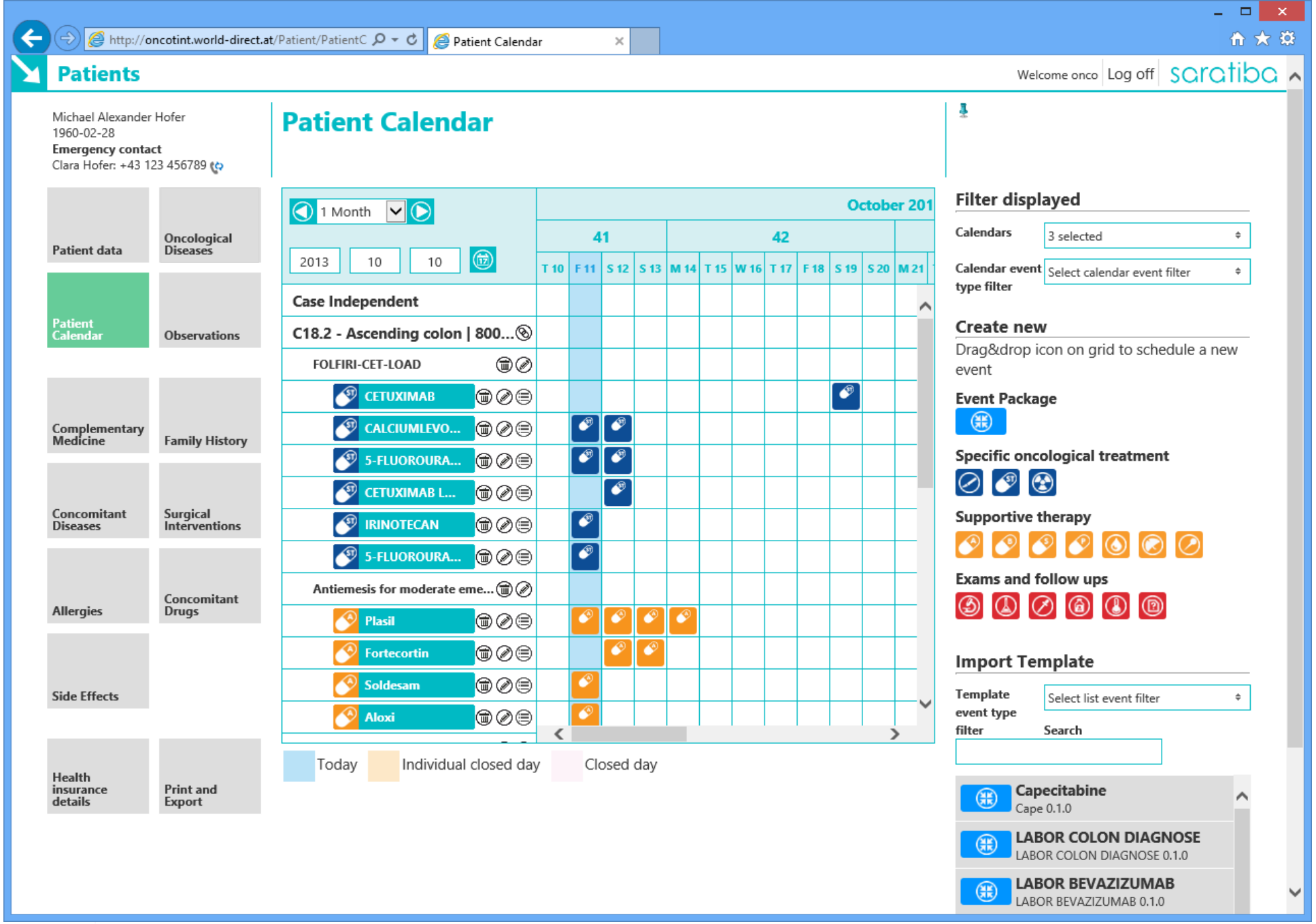
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Patient Calendar
Patient data
Oncological Diseases
Patient Calendar
Observations
Complementary Medicine
Family History
Concomitant Diseases
Surgical Interventions
Allergies
Concomitant Drugs
Side Effects
Health insurance details
Print and Export
1 Month
2013
10
10
October 201
41
42
T 10
F 11
S 12
S 13
M 14
T 15
W 16
T 17
F 18
S 19
S 20
M 21
Case Independent
C18.2 - Ascending colon | 800...
FOLFIRI-CET-LOAD
CETUXIMAB
CALCIUMLEVO...
5-FLUOROURA...
CETUXIMAB L...
IRINOTECAN
5-FLUOROURA...
Antiemesis for moderate eme...
Plasil
Fortecortin
Soldesam
Aloxi
Today
Individual closed day
Closed day
Filter displayed
Calendars
3 selected
Calendar event type filter
Select calendar event filter
Create new
Drag&drop icon on grid to schedule a new event
Event Package
Specific oncological treatment
Supportive therapy
Exams and follow ups
Import Template
Template event type filter
Select list event filter
Search
Capecitabine
Cape 0.1.0
LABOR COLON DIAGNOSE
LABOR COLON DIAGNOSE 0.1.0
LABOR BEVAZIZUMAB
LABOR BEVAZIZUMAB 0.1.0

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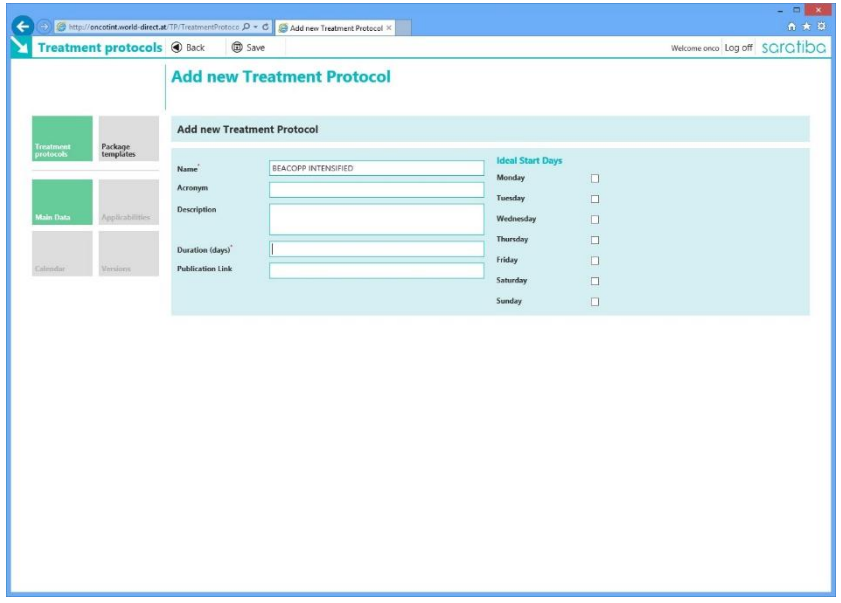
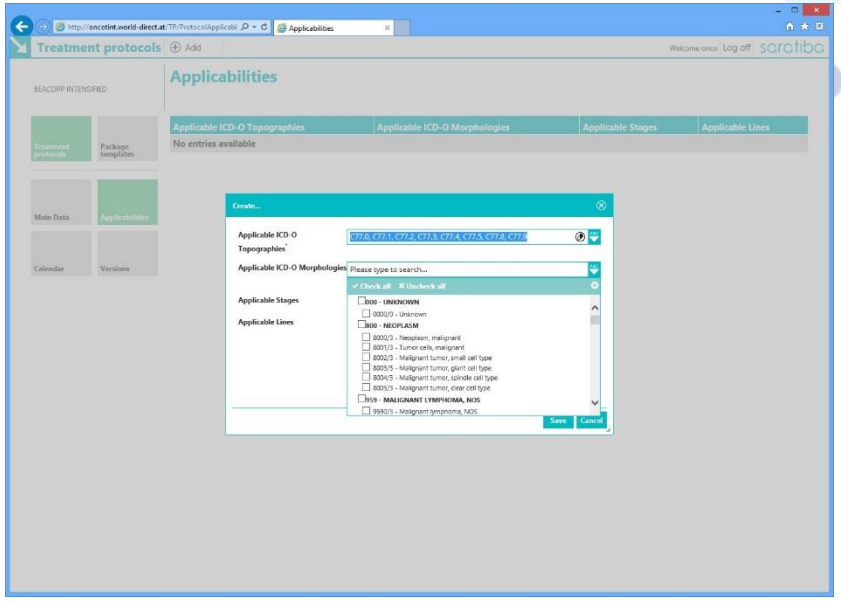
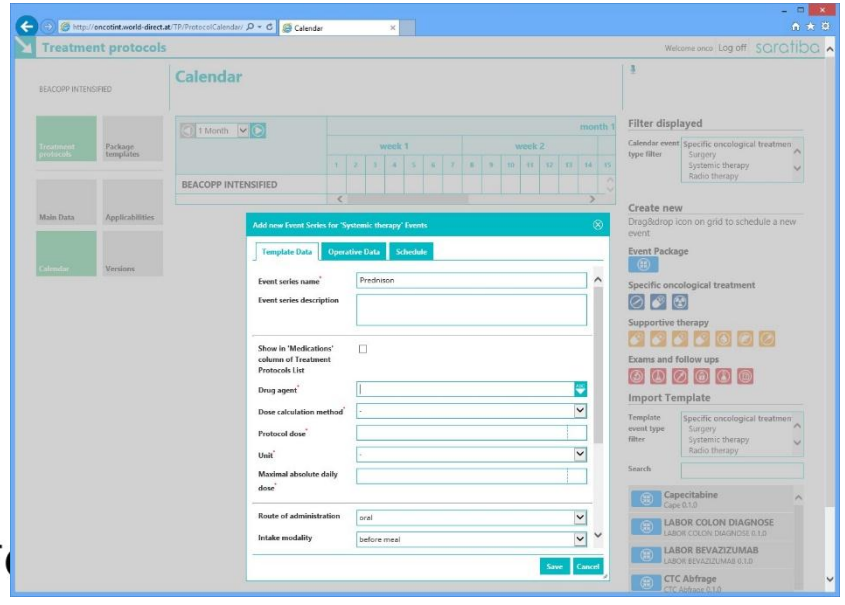
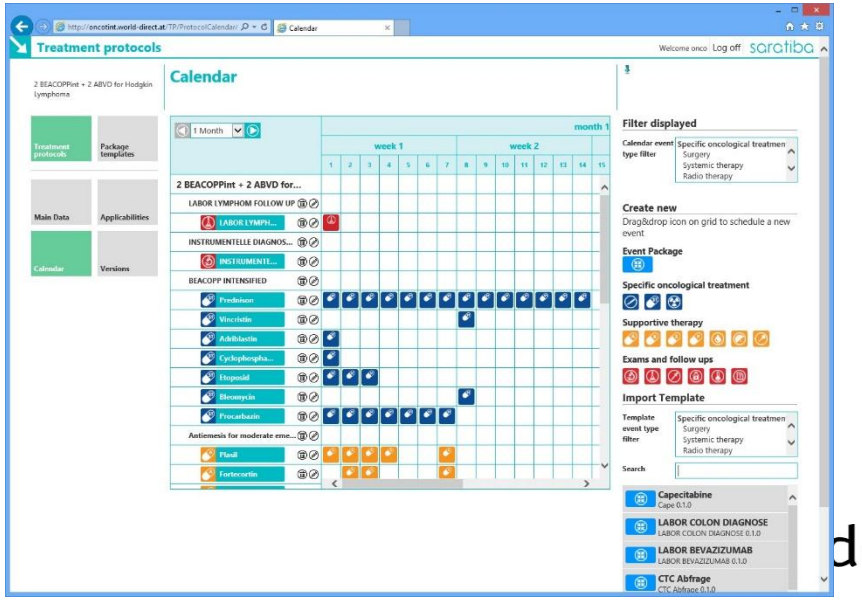
Therapie-Protokolle

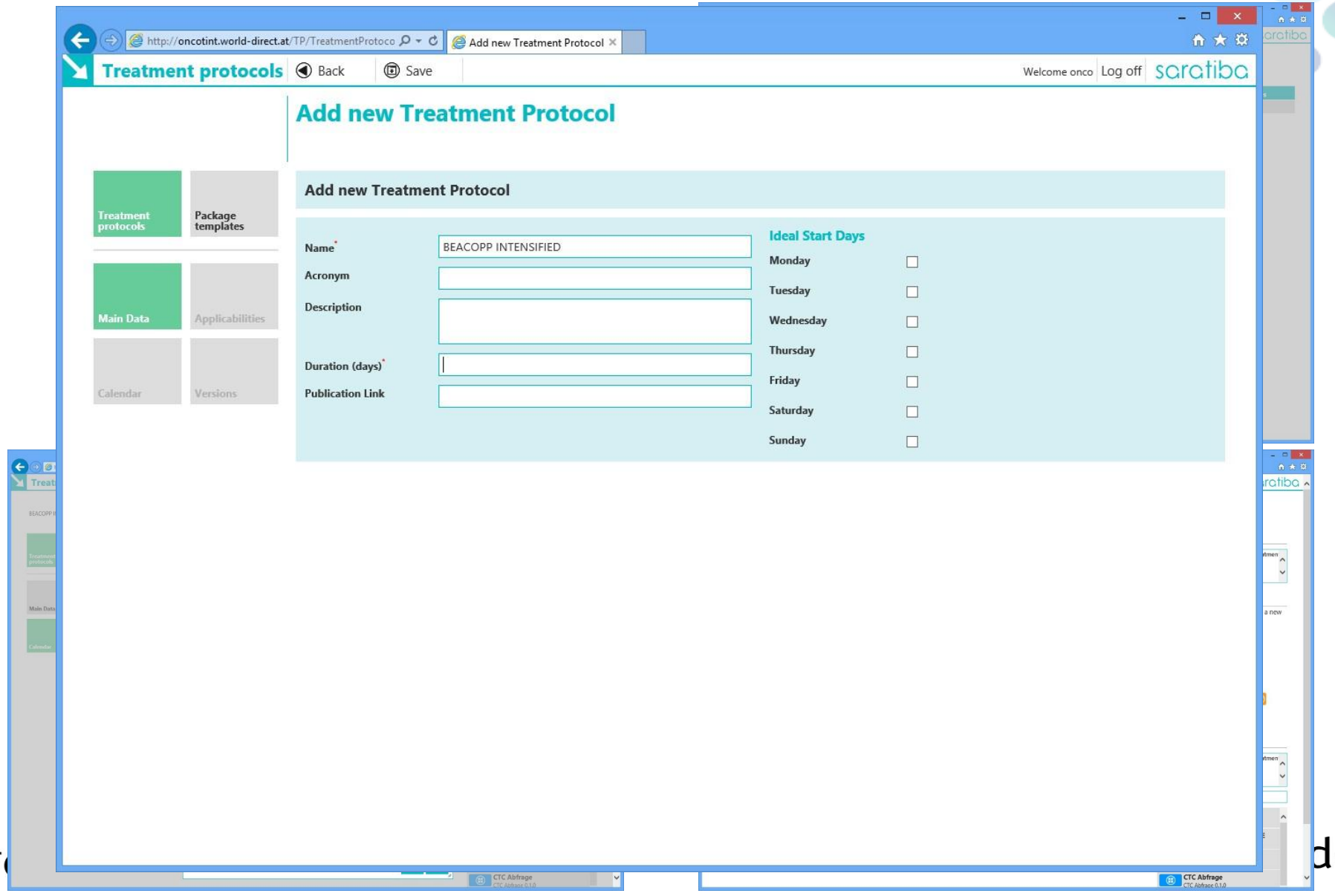




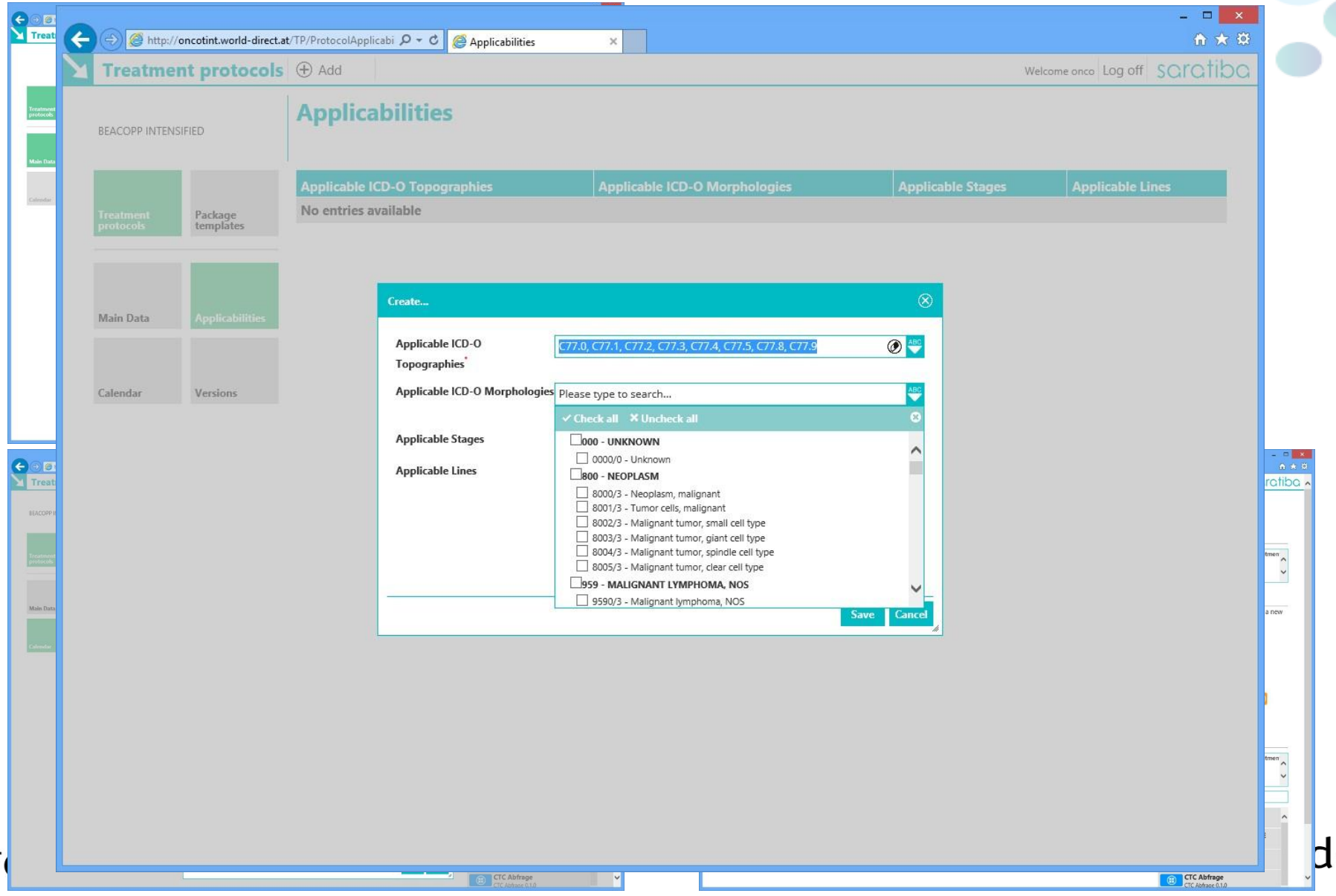




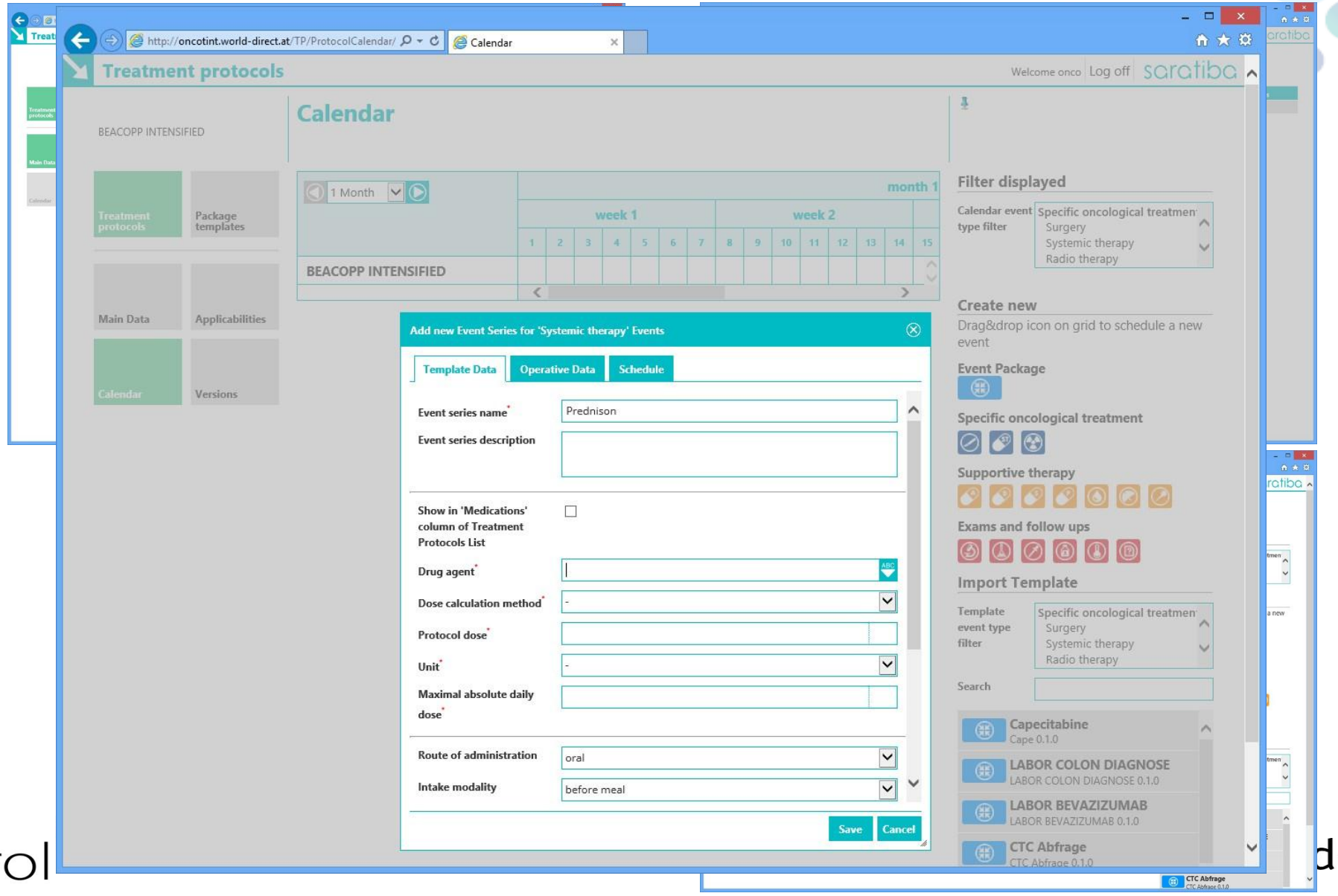
Therapie-Protokolle



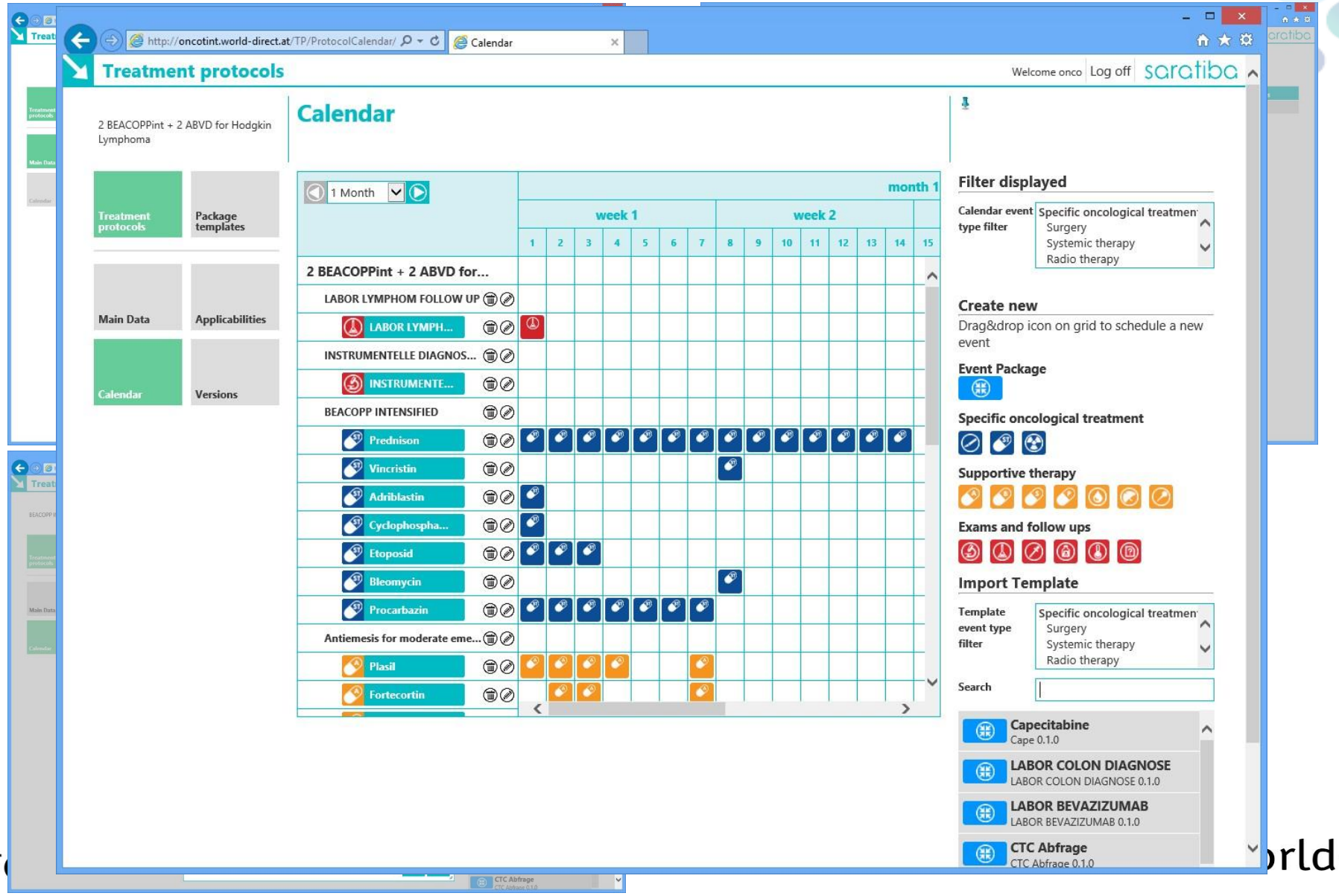
Therapie-Protokolle



Therapie-Protokolle



Therapie-Protokolle



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Erfahrungen

- Know your enemy ;-)
  - Wir sind keine Mediziner
  - Mediziner sind keine IT-Experten
  - Strukturierter Anforderungsprozess
  - Stell die richtigen Fragen
  - Transparenz

- Nütze die Zeit
  - Gute Vorbereitung auf Termine
  - Keine Übererfüllung von Anforderungen

- Agilität ist gefragt
  - SCRUM
  - Iteratives Vorgehen, Prototyping
  - Continous Integration
  - Regelmäßige Datenintegrationen

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Erfahrungen

- Stell dich gut mit der Krankenhaus-IT
  - Du bist ein „Fremdsystem“
  - Mach ihnen (zumindest in der Anfangsphase) keine unnötige Arbeit
- Dokumentation
  - Wichtig für Zertifizierung
  - Anforderungsprozess, Umsetzungsprozess, Software-Lebenszyklus
  - Dokumentation von Datenquellen
- Sei offen
  - Schnittstellen, Schnittstellen, Schnittstellen
  - Niemand gibt gern doppelt ein
  - Kataloge – strukturierte Erfassung

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Kataloge

Tumorausbreitung	ICD 0 und Histologie
Tumorstaging	Ann Arbor, TNM
Labor/Pathologie/Untersuchungen	LOINC
Medikamente/Chemotherapeutika	ATC/DDD
Chirurgische Eingriffe	ICD 9 CM
Medikamentennebenwirkungen	CTCAE
Anamnese	ICD 10
Statuserhebung	ICD 10

Patient-reported outcomes (PROs)

in clinical practice and research

Februar 2014

Evaluation of oncological treatments strategies

1. How long do patient live? – Survival
2. How much does it cost? - Pharmacoeconomics
3. How do patients experience their disease and treatment? – Quality of Life (QoL)

Patient-reported Outcomes

- PROs are an important study endpoint within clinical trials (FDA, EMA)
- Assessment of PROs within oncological routine is important for symptom monitoring and management
- Early detection of treatment needs
- Enhancing patient participation in the treatment process
- PROs provide useful information for clinical decision making
- Drug Safety Monitoring, Pharmacovigilance
- Cost-utility studies (HTA)
- Quality Assurance

Advantages of PRO monitoring in clinical routine

(Velikova et al. 2002,2004; Detmars et al. 2002; Aaronson et al. 2002 etc.)

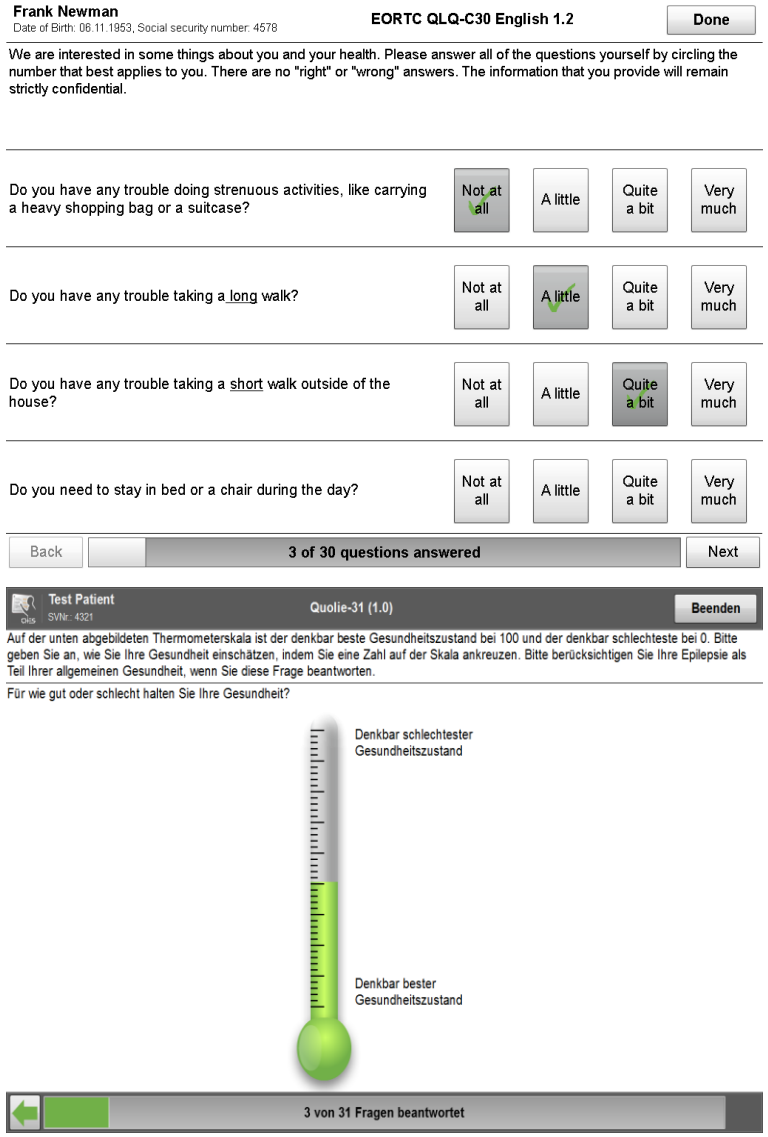
- Systematized screening of (potential) problems
- improvement of symptom management
- Improve treatment planning through individual evaluation of treatment steps
- Parameters for Clinical Decision Making
- Focusing of the individual treatment contact
- Information gain for the care team through better knowledge about the patient's subjective experience
- Improve communication, active involvement of patients
- better / faster interventions through standardized indications
- through more active involvement of individual patient data better compliance
- Ensuring continuity of care through the collection of structured information on the individual patient situation
- Long term: longitudinal database with high data quality
- Time-consuming and costly

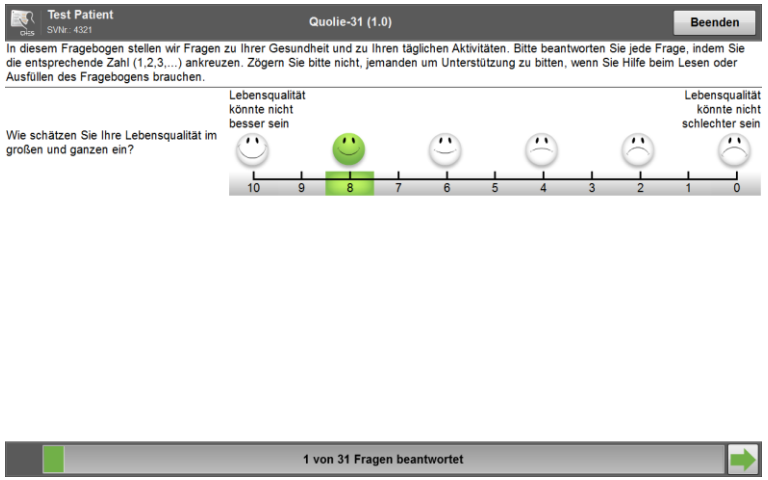
Computer-based Health Evaluation System – CHES

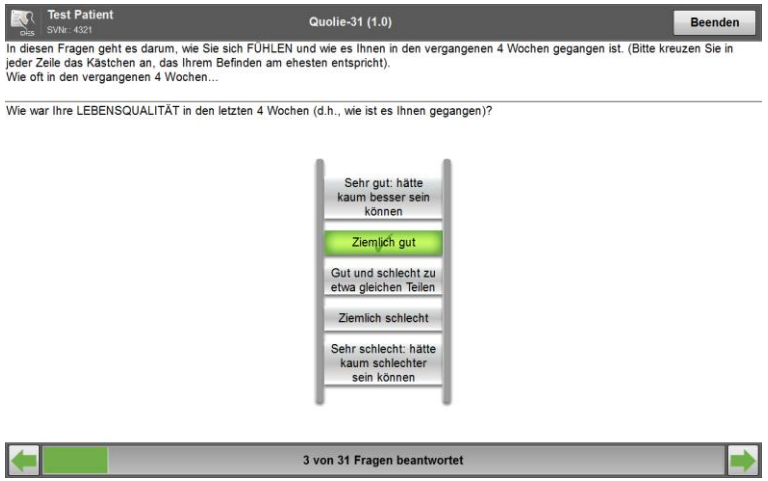
PC-Software für die Erfassung, die Auswertung und die graphische Präsentation von psychosozialen und medizinischen Daten

- Individuelle Adaptierung der Erhebungsinstrumente, der graphischen Ergebnispräsentation und der Befundberichte
- Adaptives „Flag-System“ für die Identifikation von klinisch relevanten Beeinträchtigungen/Problemen
- Graphische Verknüpfung von PRO Daten mit Krankheits-/Behandlungsverlauf
- Einfache Integration von medizinischen/psychoonkologischen Interventionen in die graphische Befunddarstellung
- Erfassung von PRO Daten auch außerhalb der Klinik (Web-Interface, iPad App)
- Datenimport/export (CIS-HL7, SPSS, tab-separated files),
- Studienmonitoring-Plugin
- Computer-adaptives Testen
- Client – Server als auch Weblösung, Datensicherheit (SSL), MySQL Datenbank

CHES Fragebogentypen





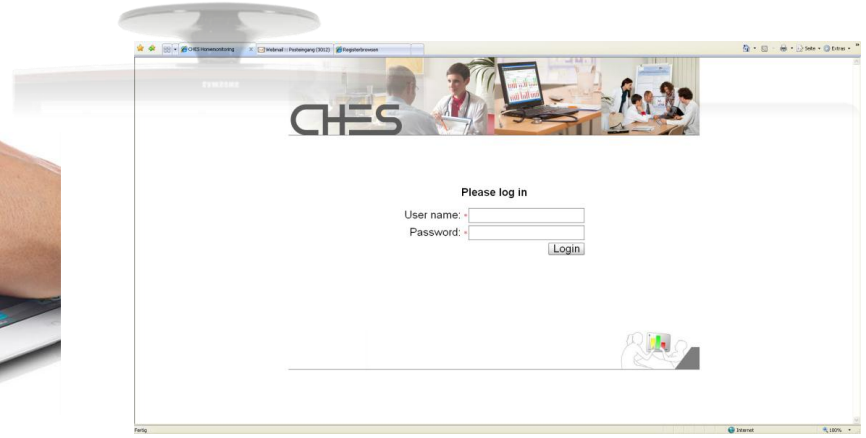


CHES - Eingabemodalitäten

Verschiedenste Erhebungsmöglichkeiten:

- PC
- Tablets (iPads, Slates, Android-Tablets)
- Terminal
- Smartphones

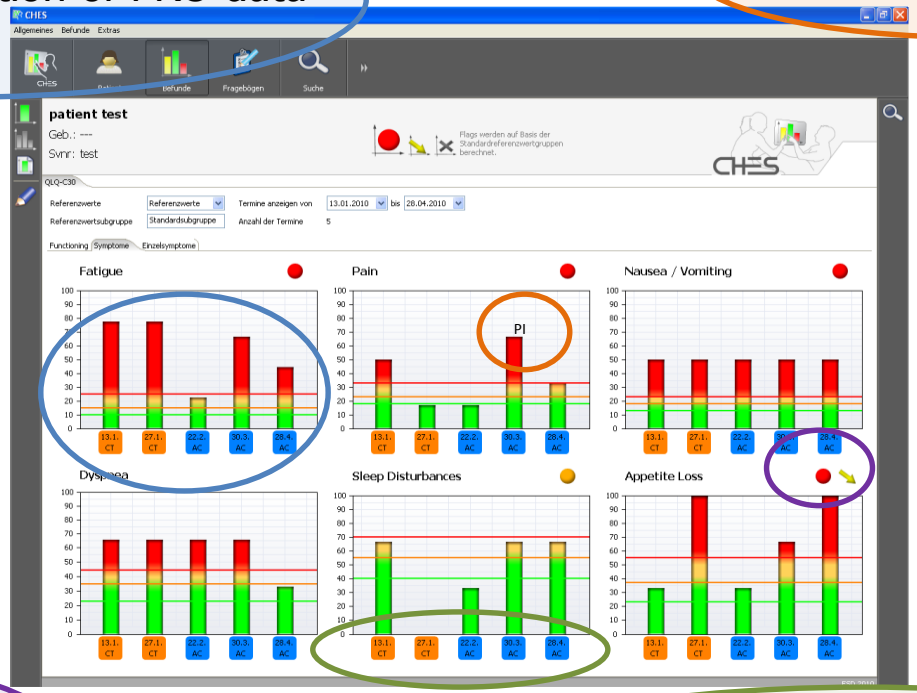
- In der Klinik
- Zu Hause via Internet (Homemonitoring)



CHES
Patientenprofil Längsschnitt

Longitudinal presentation of PRO data

Medical interventions



Flag-system based on reference values

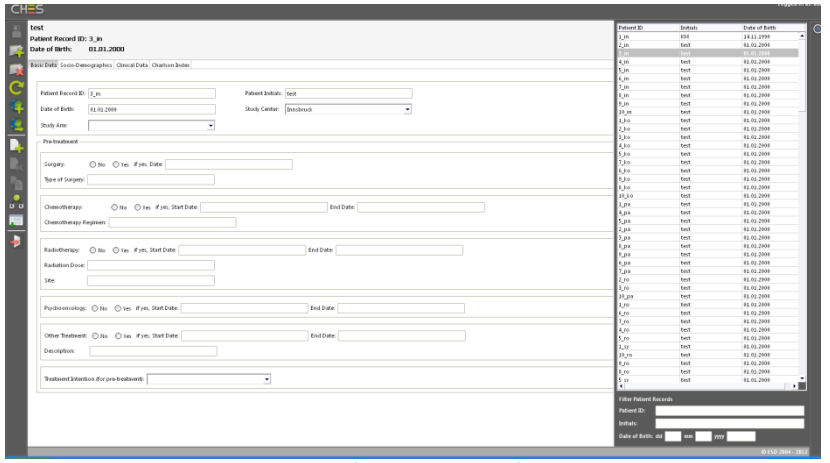
Course of symtoms and/or treatment

Patient-reported outcomes (PROs)

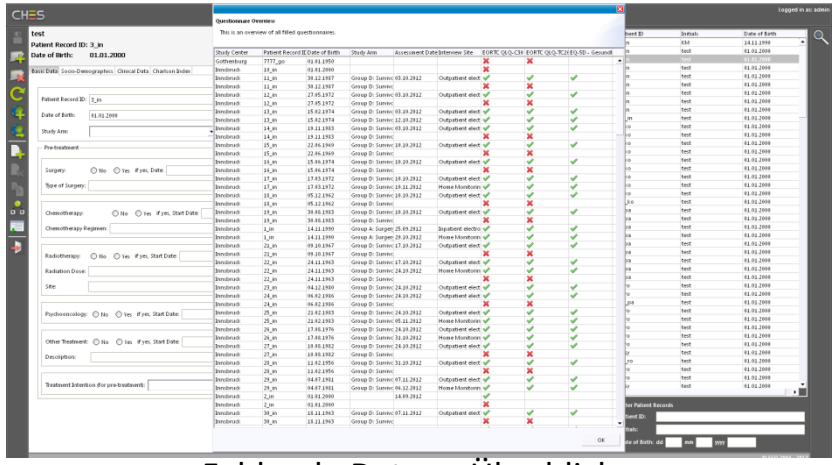
in der Forschung

EORTC QLQ-TC26
testicular cancer field study

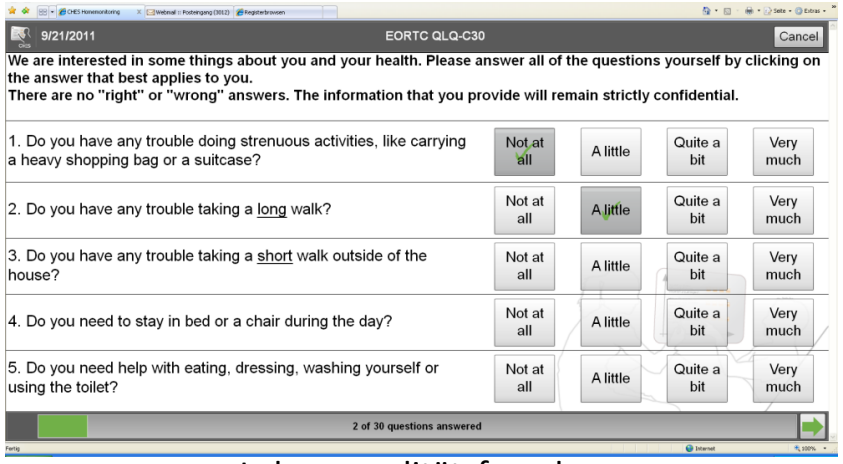
Anmeldeseite



CRF und Patientenliste



Fehlende Daten - Überblick



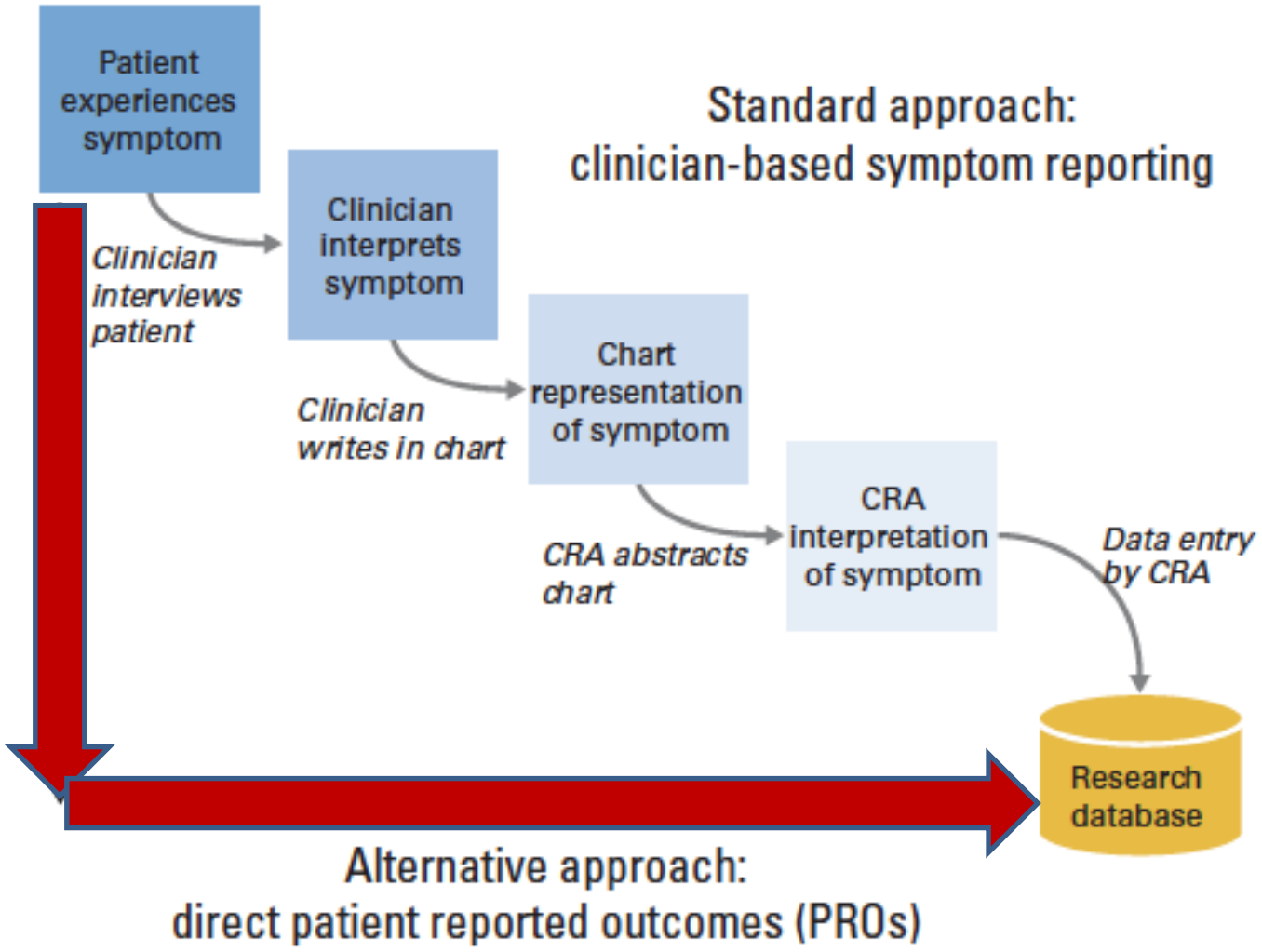
Lebensqualitätsfragebogen

Patient-reported outcomes (PROs)

in der Pharmakovigilanz

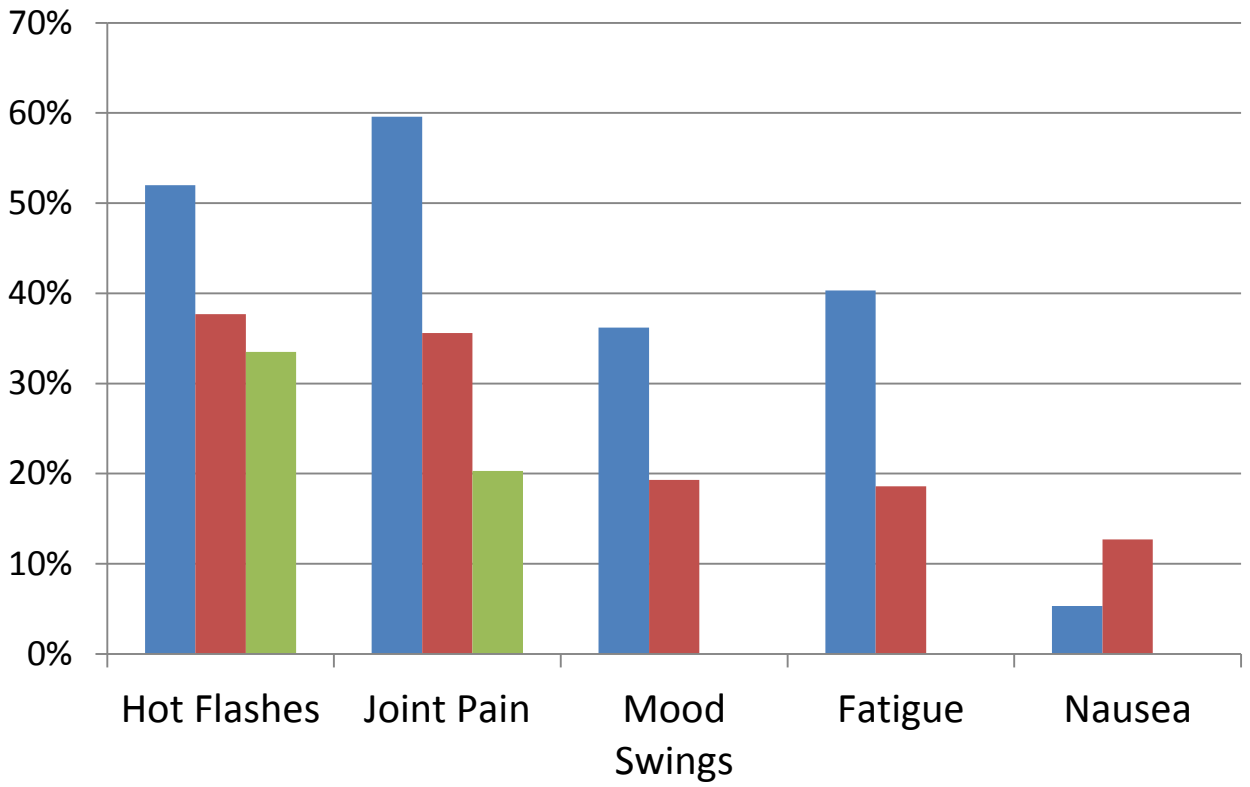
Adverse Event (AE)

Adverse Event Identifikation



aus Trotti A, Colevas D, Setser A and Basch E (2007) JCO

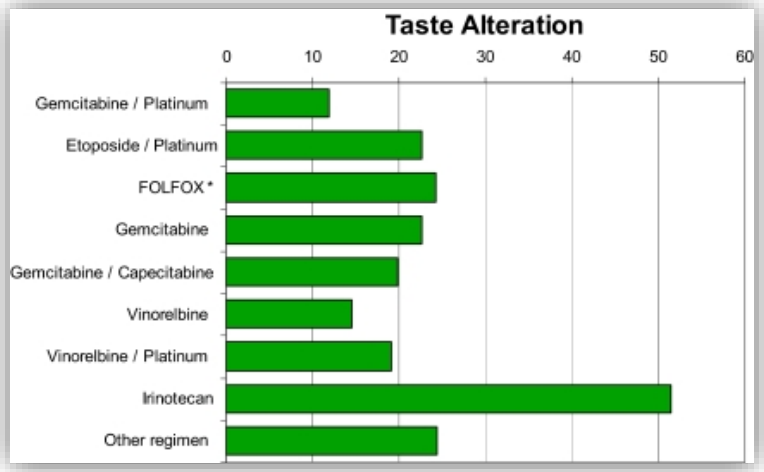
PROs ergaben unterschiedliche (meist höhere) Symptomprävalenzen verglichen mit den Behandlerfremdratings



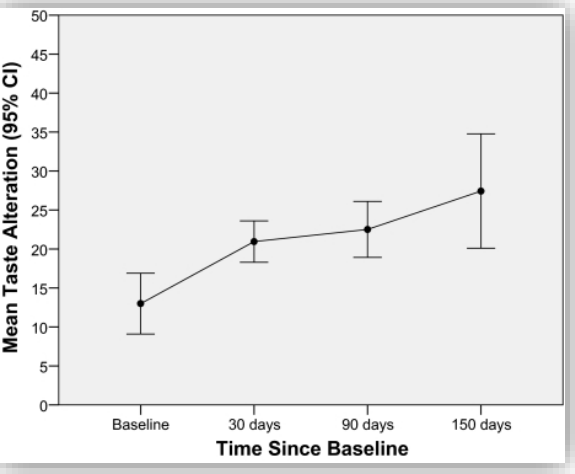
Patient-reported outcomes (PROs)

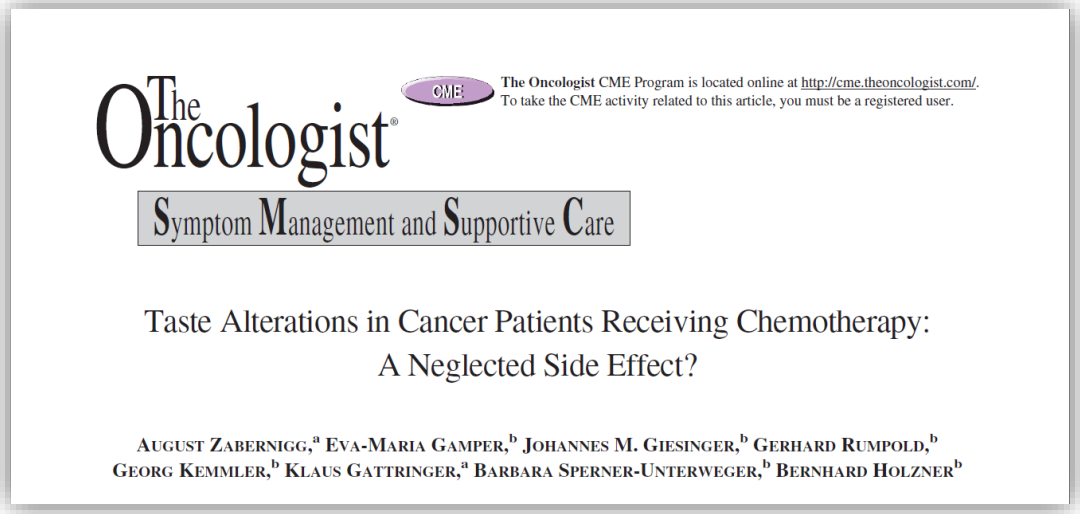
in der klinischen Praxis

Geschmacksstörungen bei ChemotherapiepatientInnen



Beispiel für eine wissenschaftliche Analyse der Daten, die am BKH Kufstein in der klinischen Routine erhoben wurden




The Oncologist

CME

The Oncologist CME Program is located online at http://cme.theoncologist.com/. To take the CME activity related to this article, you must be a registered user.

Symptom Management and Supportive Care

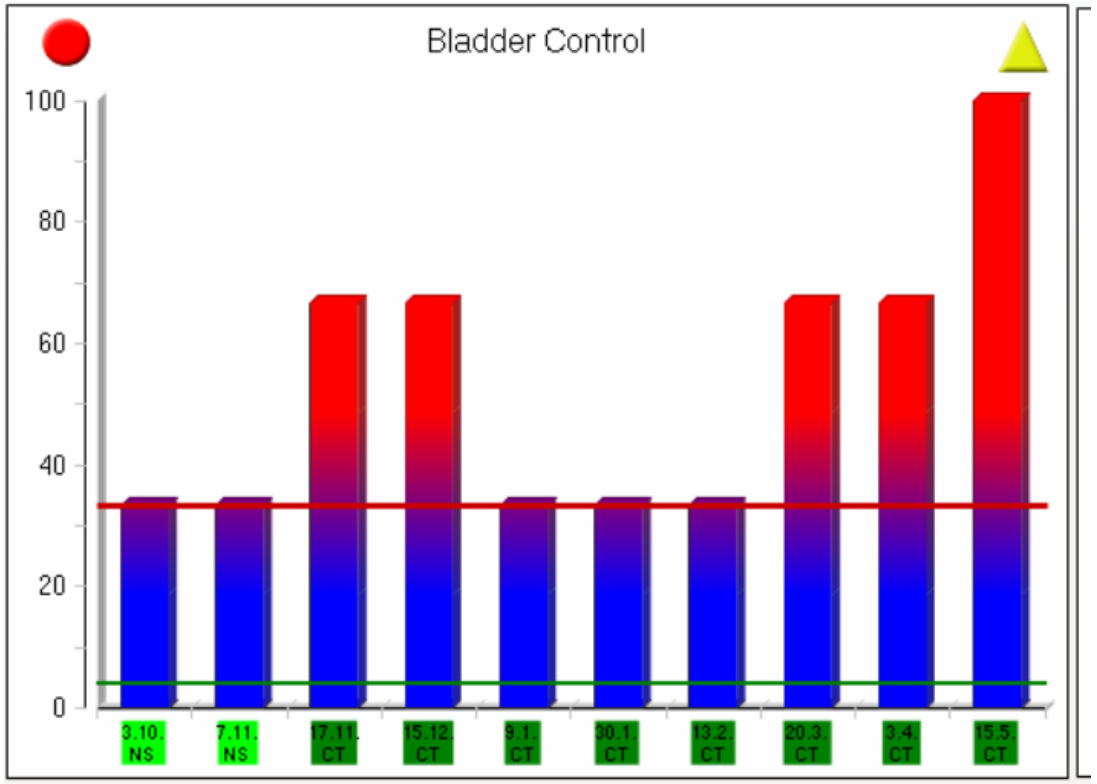
Taste Alterations in Cancer Patients Receiving Chemotherapy: A Neglected Side Effect?

AUGUST ZABERNIGG,[a] EVA-MARIA GAMPER,[b] JOHANNES M. GIESINGER,[b] GERHARD RUMPOLD,[b] GEORG KEMMLER,[b] KLAUS GATTRINGER,[a] BARBARA SPERNER-UNTERWEGER,[b] BERNHARD HOLZNER[b]

Patient example

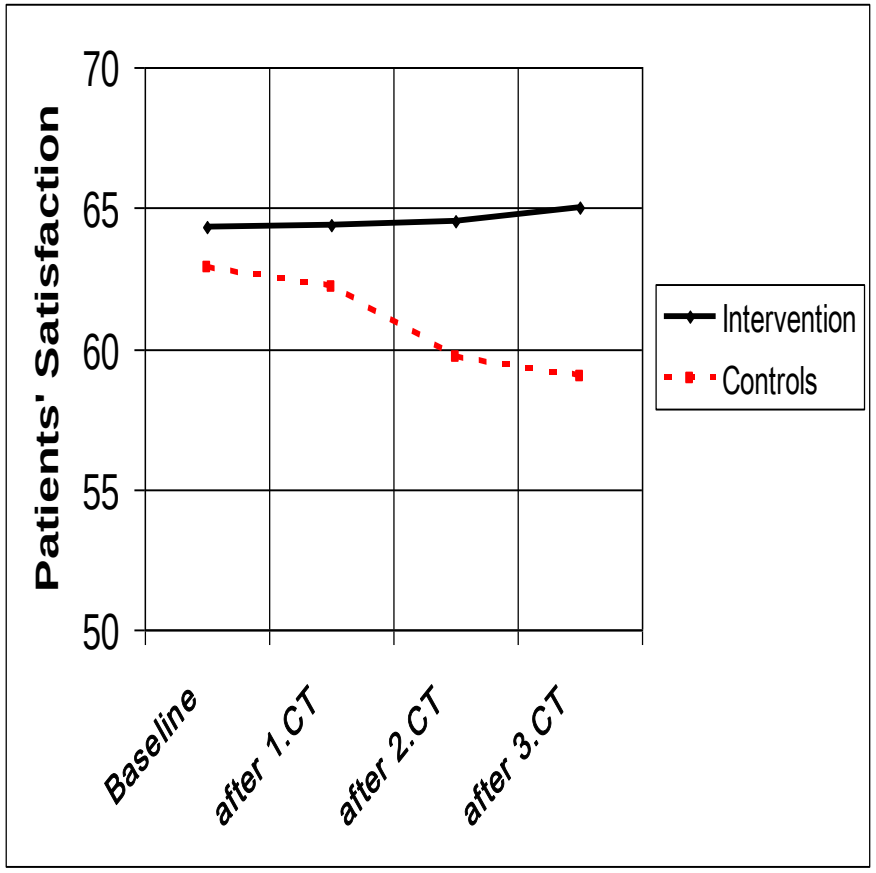
Brain tumour patient in aftercare:

– Bladder Control as an unrecognized problem

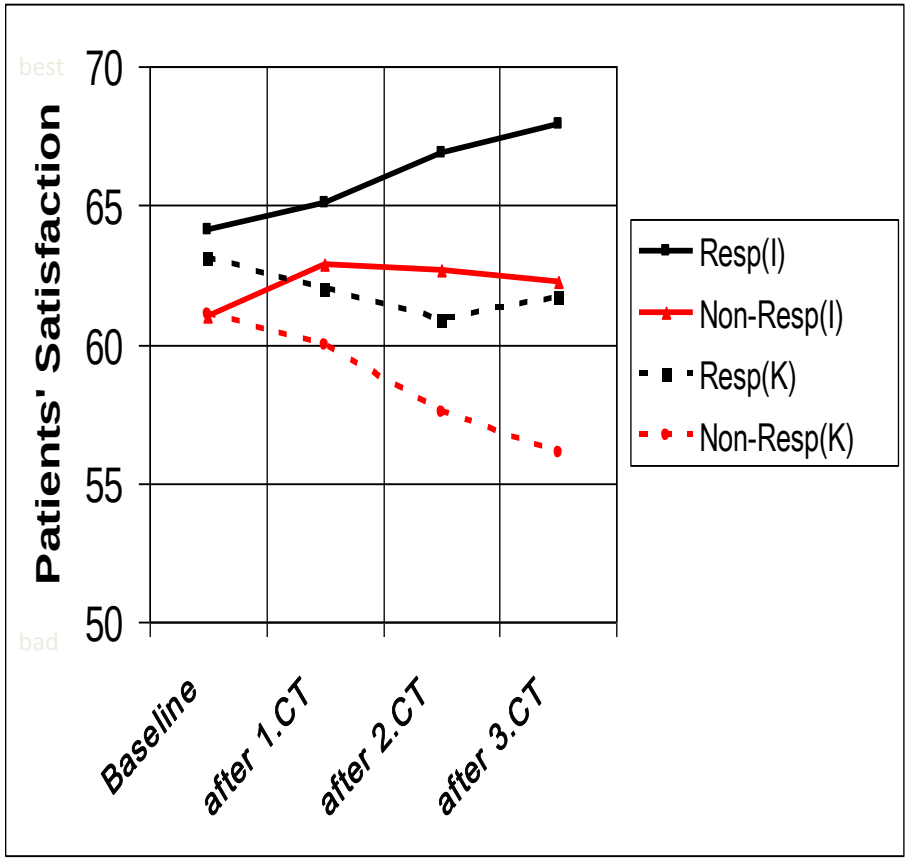


Clinical Routine

Patients‘ Satisfaction: Intervention- vs. Control group



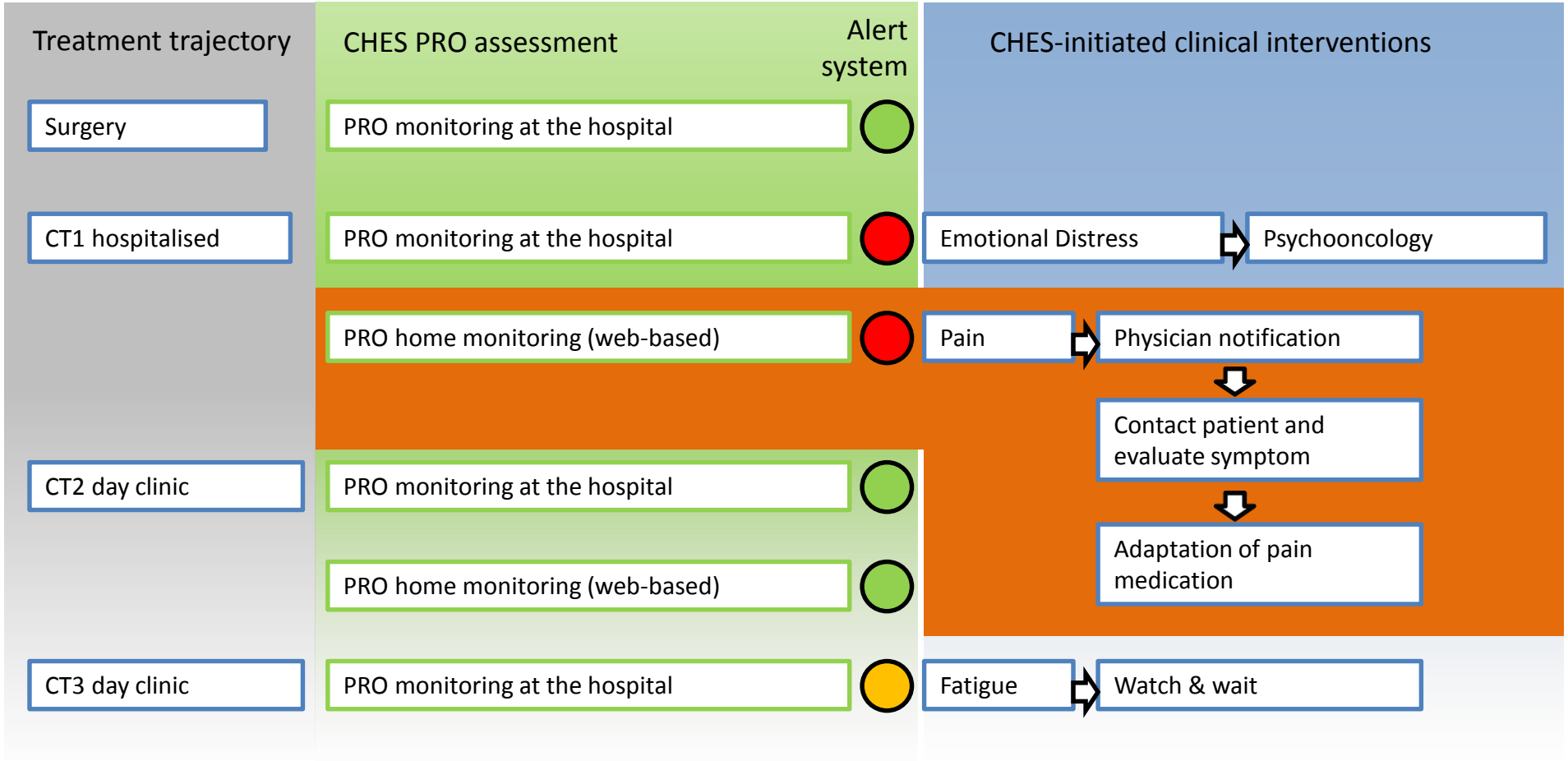
Co-variate: tumor status



Patient-reported outcomes (PROs)

Homemonitoring von somatischen und psycho-sozialen Symptomen und Behandlungs-nebenwirkungen bei onkologischen Patienten (ONKO-TEL)

ePRO's
Integrated in the clinical procedure



Erste Ergebnisse

680 Erhebungszeitpunkte

	zu Hause MW	Klinik MW	p
Physical Functioning	76.8	80.0	<.001
Role Functioning	59.3	63.4	.002
Social Functioning	69.9	74.1	<.001

→ via Home-Monitoring berichten PatientInnen höhere Belastungen

Nausea/Vomiting	11.4	8.6	.005
Dyspnea	23.8	21.3	.036
Sleep Disturbances	31.1	27.0	.013
Appetite Loss	20.8	16.4	.004
Constipation	27.8	18.5	<.001
Taste	23.1	16.9	<.001

Patient-reported outcomes (PROs)

Und Health Technology Assessment (HTA)

The electronic PORPUS (https://ches.at/e-porpus/)

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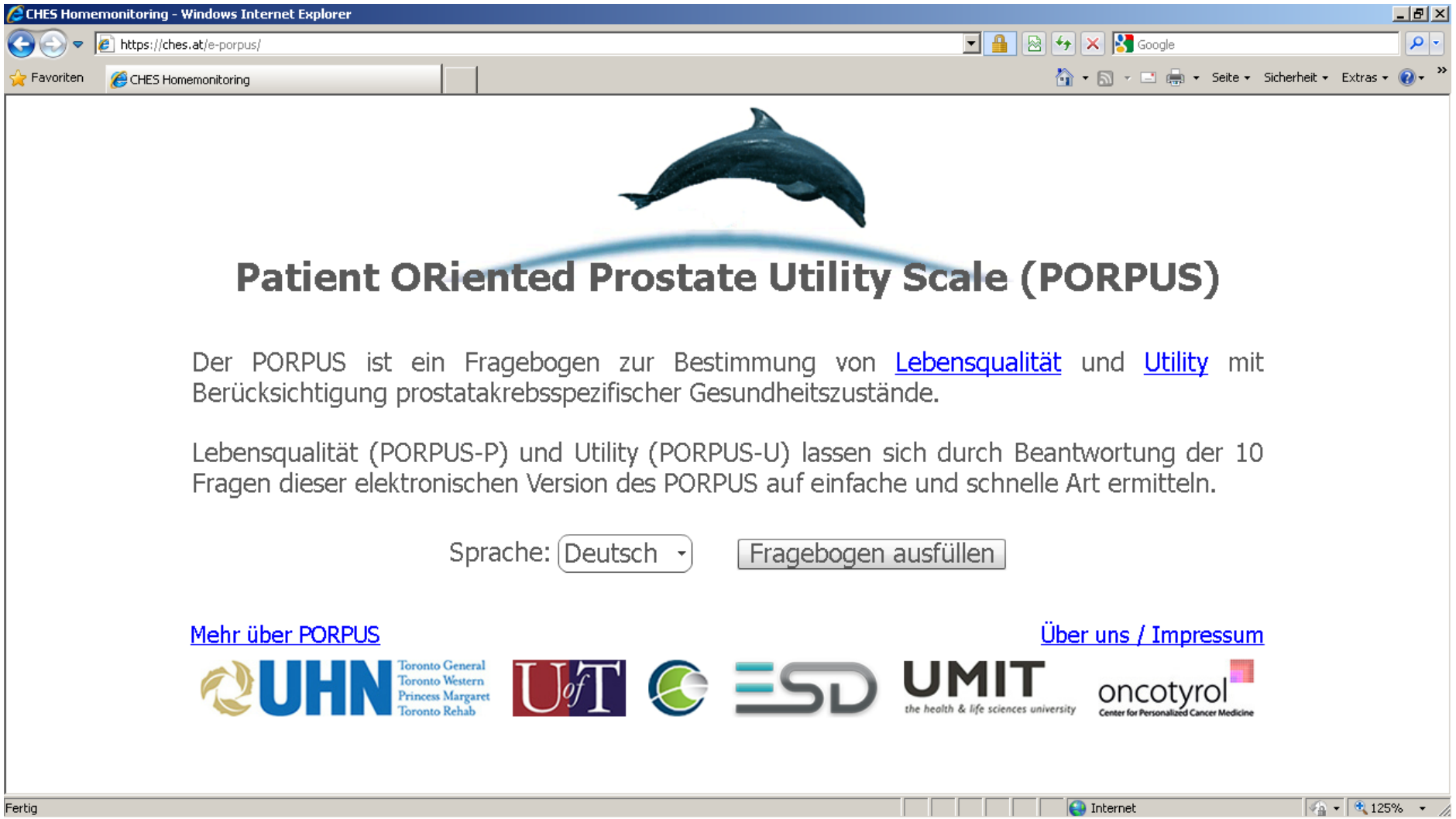

Concept of the Personalized Decision Tool

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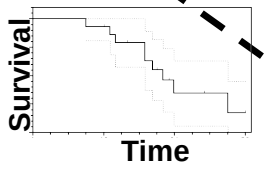
Phase I — Phase II

Tyrol. Ca. Registry
→ Incidence and mortality data

Epi. studies
→ Predictive and prognostic functions

OT-Area 2/3 Clinical and diagnostic data

Individual men
→ Individual risk profiles and preferences



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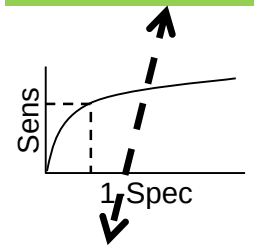
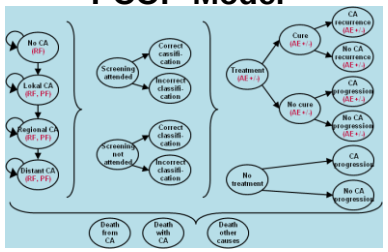


PCOP-Model



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Advice to individual men and their physicians

To assess technologies and answer core HTA questions:

1. Is it effective and efficient?
2. Can it be modified?
3. Is there a suited subpopulation?

To screen, or not to screen?

PCOP Model – Outputs

oncotyrol
Center for Personalized Cancer Medicine

Time horizon 120 years (1440 months, extrapolated life table), 1 Mio trials, seeding

	No screening	One-time screening at 55y	One-time screening at 65y	One-time screening at 75y	Interval screening every 4y, 55-75y
Lifetime risk of PCa diagnosis (%)	18.9	19.2	21.5	30.7	35.6
Lifetime risk of PCa diagnosis by screening (%)	-	1.4	7.1	19.9	30.4
Lifetime risk of irrelevant PCa diagnosis (Overdiagnosis) (%)	-	0.3	2.6	11.8	16.7
Lifetime risk to die from PCa (%)	3.7	3.5	3.0	3.1	2.2
Lifetime gained vs. no screening (Days)	-	8.5	15.6	9.2	29.4
Quality adj. lifetime gained vs. no screening (QALDs)	-	5.0	1.8	-17.7	-34.4
Lifetime cost per man (EUR)	3830	3938	4421	6158	6775
Discounted ICUR (EUR per QALY gained) discount rate =3%	-	63447	dominated	dominated	dominated

Patient-reported outcomes (PROs)

Verwendung und Nutzen in der klinischen Praxis, in der Wissenschaft und in der Qualitätssicherung

Februar 2014