Implementation of proactive risk analysis in radiotherapy with myQA PROactive. Case study: surface guided DIBH breast radiotherapy

Serenella Russo

AUSL Toscana Centro, S. Maria Annunziata Hospital -Florence

serenella.russo@uslcentro.toscana.it

Background

RT clinic in a public community hospital
(S. Maria Annunziata Hospital, Florence)

- 2 LINACs
- Risk analysis performed since 2010
- Investigated workflows: 3D CRT, IMRT, VMAT, **SGRT** DIBH, SBRT (in progress)
- Methods: FMEA, 3 parameters, scales 1-5 (local guidelines)
- Tools: Word\Excel

“Home made“ FMEA Analysis SGRT DIBH

AZIONI	RESPONSABILITA'	DOCUMENTI DI SUPPORT	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
TC Breath Hold (BH):										
La paziente indossa gli occhiali per la visualizzazione del proprio respiro	TSRM	Procedure interne	POSIZION NON CORRETTO	scarsa compliance paziente	NON CORRETTA VISUALIZZ SCHERMO	2	2	1	6	Verifica della visualizzazione dello schermo

ELABORAZIONE PIANO TRATTAMENTO CORPO MAMMARIO BH

AZIONI	RESPONSABILITA'	DOCUMENTI DI SUPPORT	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
			individuazione iso/ Errore nella	sulla cartella di	DTF e frazionamento					Verifica durante approvazione del

ELABORAZIONE PIANO TRATTAMENTO CORPO MAMMARIO BH

AZIONI	RESPONSABILITA'	DOCUMENTI DI SUPPORT	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
Elaborazione ed invio DRR	FISICO	TPS	Errato/assente invio Invio delle DRR non ottimali	Mancato/Errato invio DRR Non impiego del giusto filtro	DRR non idonea alla verifica con IP in fase di trattamento	3	3	2	18	Importazione e verifica DRR il giorno precedente a quello di trattamento

CENTRAGGI

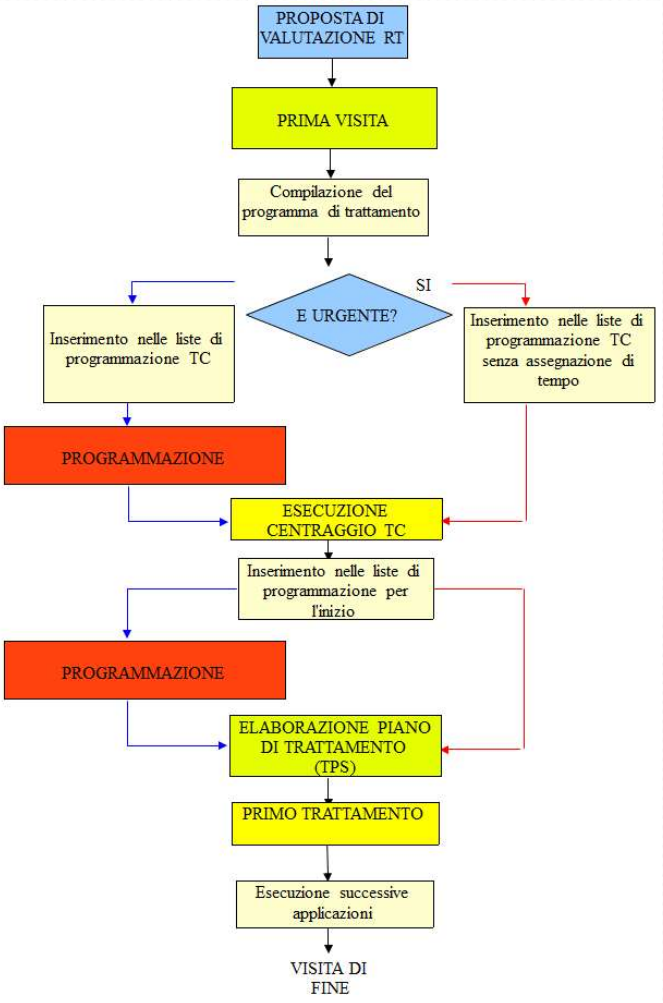
- III

PRIMA SEDUTA TRATTAMENTO BH / SEDUTE SUCCESSIVE - III

PRIMA SEDUTA TRATTAMENTO BH / SEDUTE SUCCESSIVE - IV

AZIONI	RESPONSABILITA'	DOCUMENTI DI SUPPORT	RISCHI	CAUSE	EFFETTI	G	F	R	IPR	Barriere
Acquisizione la base-line giornaliera	TSRM	Catalyst	Base line non corretta	Posizione punto di riferimento non ottimale / Movimenti paziente	Mancata riproducibilità apnea	3	2	1	6	Training paziente / Ottimizzazione parametri di acquisizione telecamera
Esecuzione apnea per verificare la correttezza del respiro nei confronti delle soglie	TSRM	Catalyst	Soglie non valide	Incapacità paziente a raggiungere soglie / Scarsa compliance paziente /Ansia	Mancata riproducibilità apnea / Eccessiva durata seduta	3	2	1	6	Training paziente
Valutazione dei parametri di riferimento del segnale respiratorio ed eventuale modifica	MEDICO/FISICO	Catalyst	Soglie non valide	Variazione della posizione del punto di riferimento per il controllo del respiro	Possibile variazione apnea rispetto a centraggio TC	3	2	3	18	Verifica con Portal Imaging / Mantenimento della stessa differenza tra soglia inferiore e base line ed ampiezza della
Acquisizione immagini portali	TSRM	Iview	Esecuzione dell'immagine portale in apnea non corretta / Ritardo partenza fascio	Mancato collegamento / errata selezione parametri di acquisizione	Ripetizione dell'esecuzione dell'immagine portale	3	3	2	18	Presenza di 2 TSRM e medico
Valutazione immagini portali	MEDICO	TPS / Iview	Errata valutazione	Bassa qualità dell'immagine portale/DRR	Il volume irradiato può essere diverso da quello pianificato	4	2	1	8	Manutenzione pannello iview/ riesportazione DRR
Firma in cartella IP e accordo con il sistema ottico	MEDICO	Cartella trattamento	Mancanza firma e valutazione accordo	Dimenticanza / carico di lavoro	Mancato passaggio informazioni	3	2	2	12	Presenza di 2 TSRM e medico
Erogazione trattamento BH	TSRM	Mosaiq / Catalyst	Difficoltà di erogazione	Mancato collegamento / Scarsa compliance paziente	Mancato avvio del fascio	3	3	1	9	Presenza di piano a RL approvato per back up
Congedo paziente	TSRM		Caduta dal lettino di trattamento Urto con la testata	Il paziente si alza troppo presto	Danno accidentale	5	1	1	5	Istruzione del paziente/Controllo di 2 TSRM cin sistema telecamere /
Firma della seduta in cartella di trattamento	TSRM	Cartella di trattamento	Mancato conteggio seduta	Carico di lavoro Dimenticanza Cartella presa per visita	Errore nel conteggio della dose e del numero di sedute	2	3	1	6	Registrazione sedute effettuate su mosaiq Revisione cartelle
Rendicontazione prestazione mosaiq	TSRM	Mosaiq	Mancata /errata rendicontazione	Carico di lavoro Dimenticanza	Errata rendicontazione	3	2	1	4	Presenza pacchetti di attività /Verifica a fine turno TSRM

AZIONI	Barriere
Effettuazione foto di ri	Presenza di 2 TSRM
	Identificazione del paziente tramite richiesta del nominativo al paziente
Posizionamer	Presenza 2 TSRM
Aggiorname	
Apertura fascio Rt e Ric riferimento in BH in Catal	Controllo nome fascio/ Adozione template TPS con nome fascio differenziato
Esecuzione spostamenti su durante l'apnea per ripro	Ottimizzazione parametri superficie / Training paziente / Consulenza fisico
Passaggio in modalità Mot	Verifica segnale respiratorio all'interno delle soglie / Training paziente / Consulenza fisico
Variazione/conferma del pur il controllo del respiro se n	Acquisizione TC ampia / ottimizzazione parametri di acquisizione telecamera



Flowchart

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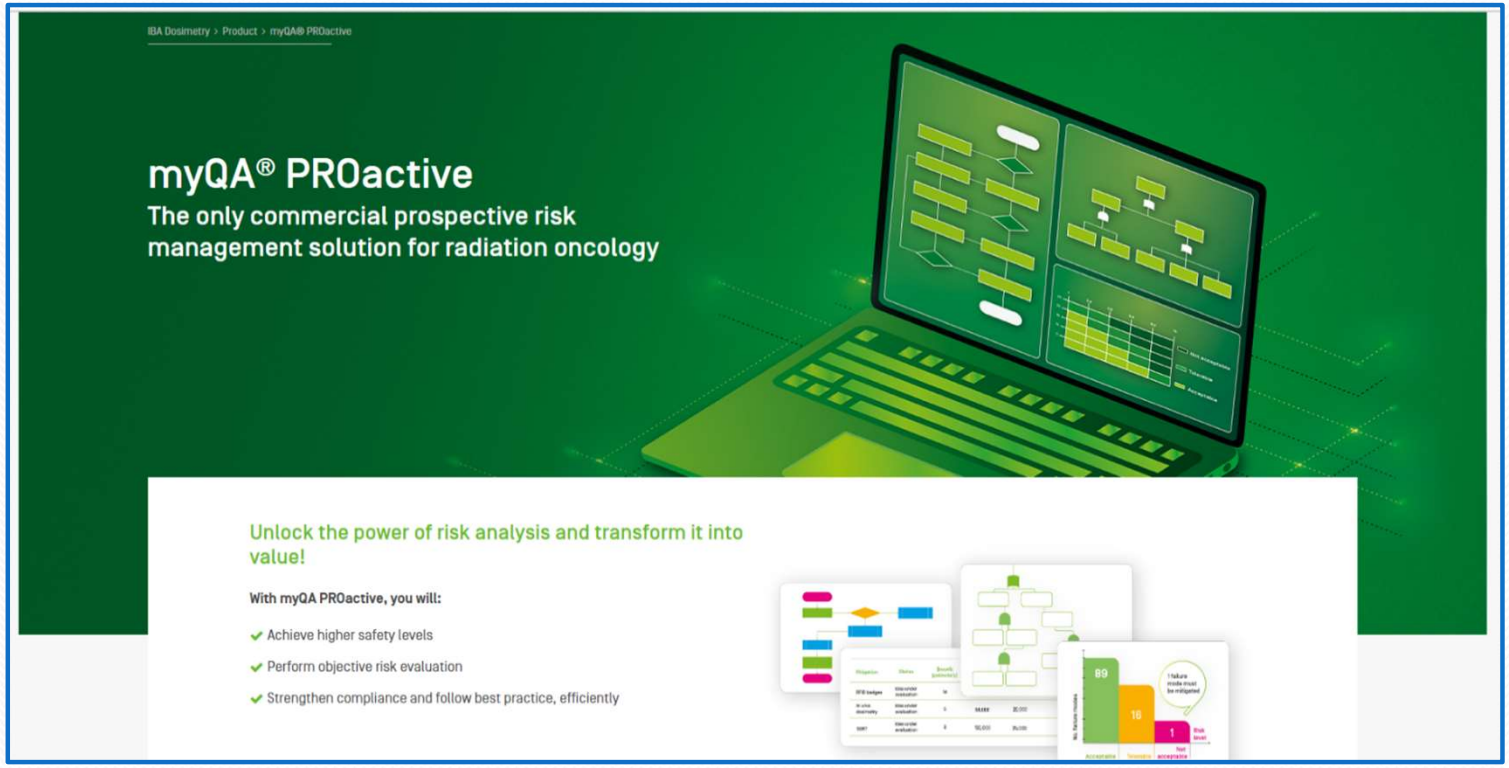
Automated tools for clinical risk management

myQA PROactive

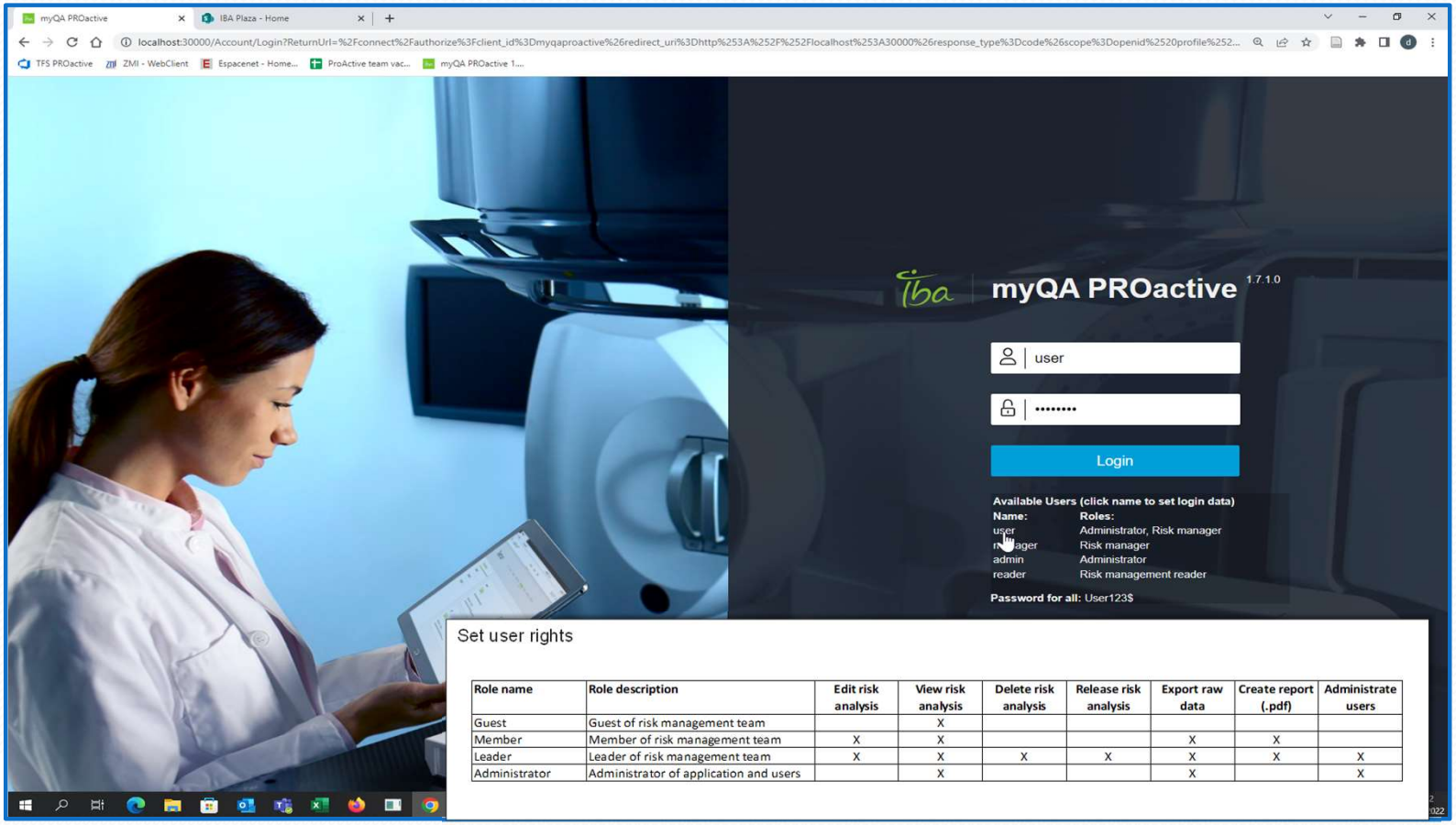
- Dedicated to prospective risk analysis
- Optimized for clinical applications
- Prototype tested by >20 clinical partners worldwide



Automated tools for clinical risk management

myQA PROactive

- Browser based
- Local installation (PC or server)
- Multi-user access with personal credentials



Set user rights

Role name	Role description	Edit risk analysis	View risk analysis	Delete risk analysis	Release risk analysis	Export raw data	Create report (.pdf)	Administrate users
Guest	Guest of risk management team		X					
Member	Member of risk management team	X	X			X	X	
Leader	Leader of risk management team	X	X	X	X	X	X	X
Administrator	Administrator of application and users		X			X		X

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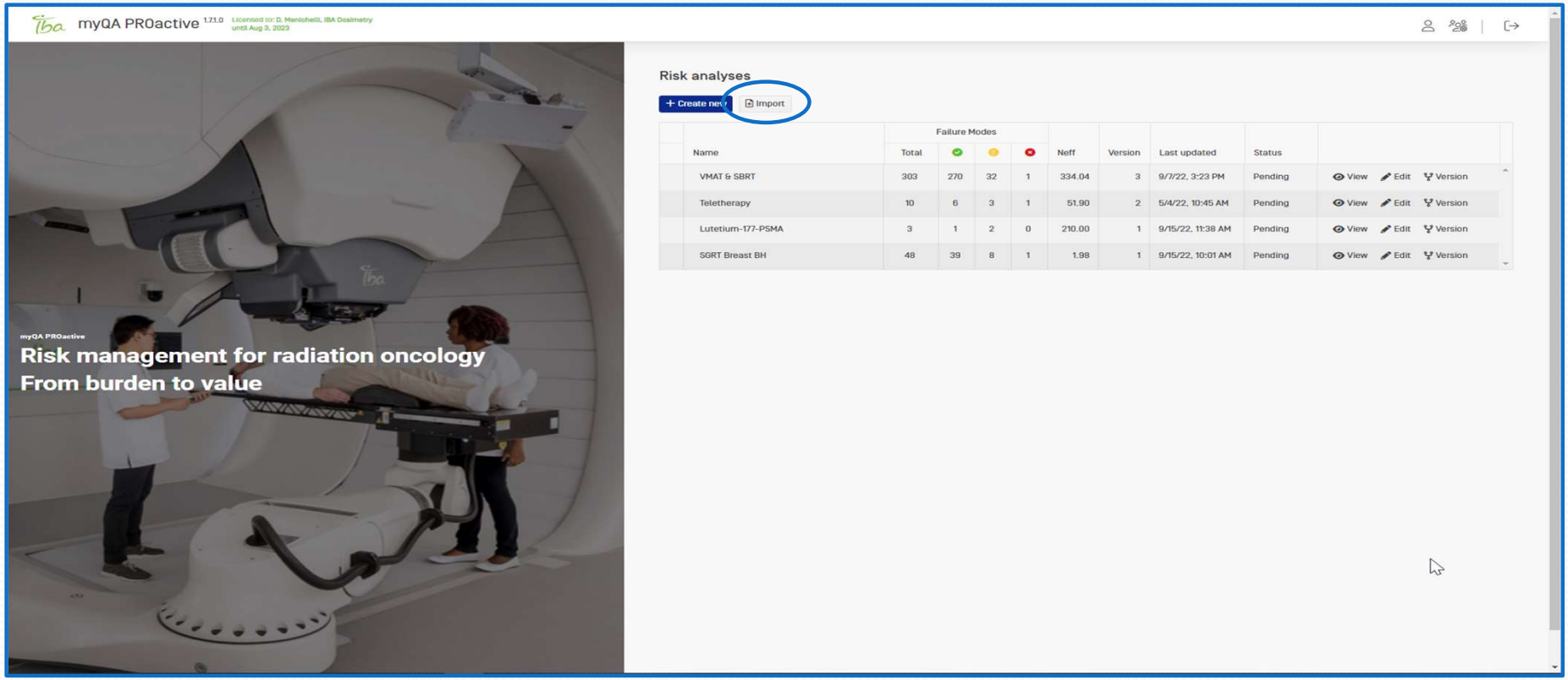
Automated tools for clinical risk management

myQA PROactive

- **Templates** fully editable elaborated by clinical partners
- FMEA excel spreadsheet can be imported with few formatting steps

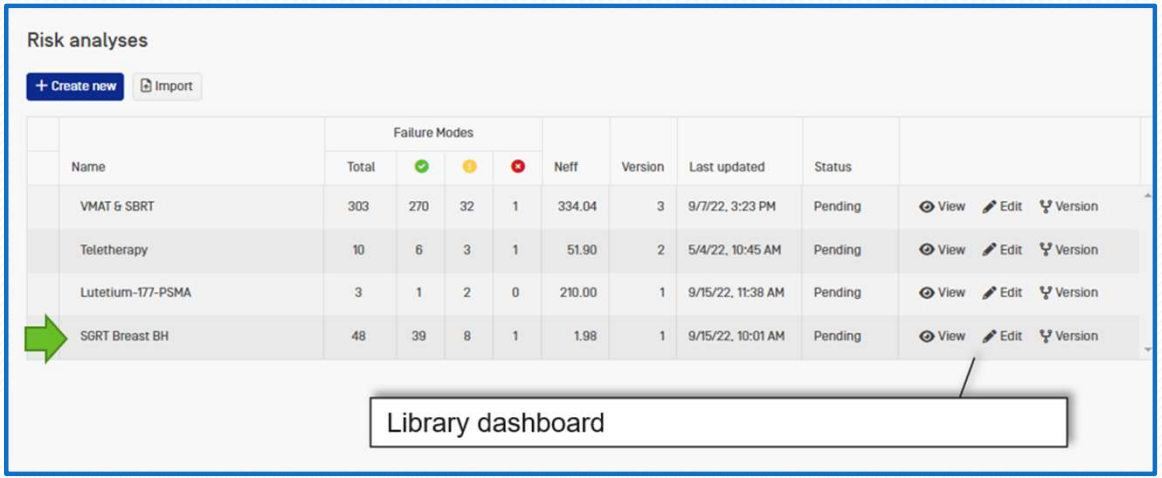


Automated tools for clinical risk management

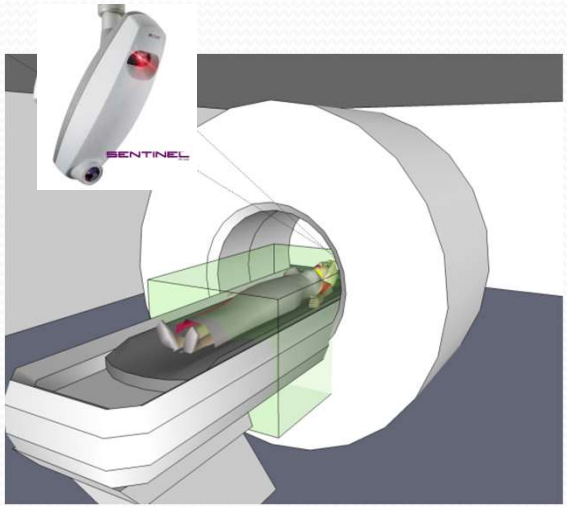
myQA PROactive Templates

Templates include a typical description of:

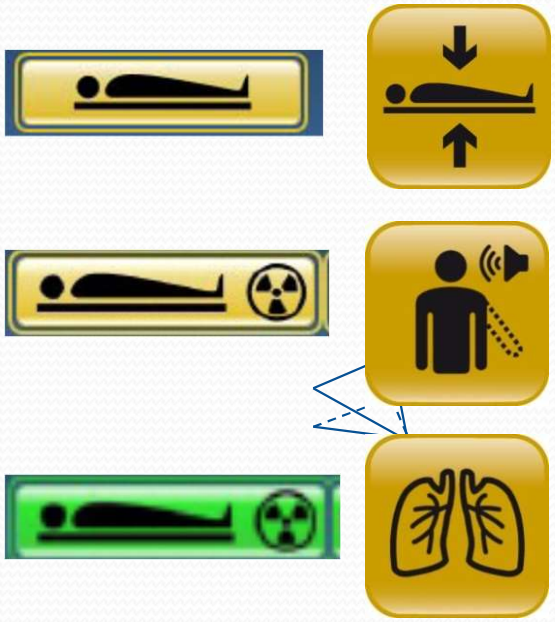
- Workflow (step list and flowchart)
- Failure modes
- Examples of Failure mode evaluation (O, S, D): provided, with context (the clinical setting in which they have been generated)
- Risk reduction measures in place by-default in most clinics
- Example of quality measures which can be added



Surface guided DIBH breast radiotherapy



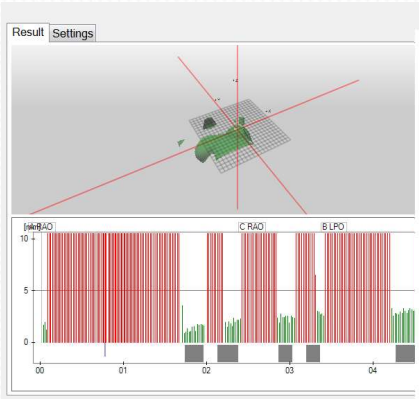
CATALYST HD

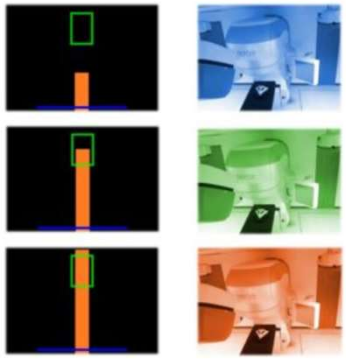


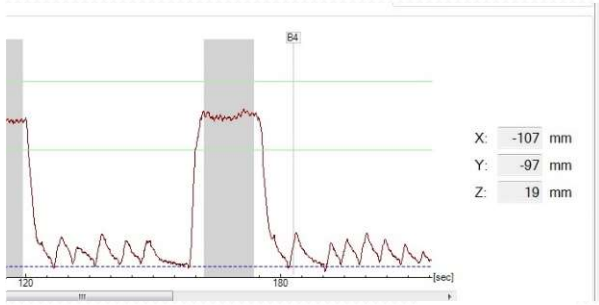
Posture adjustment
Patient Setup

Intrafraction
Monitoring

Respiratory Gating







Visual Coaching Systems

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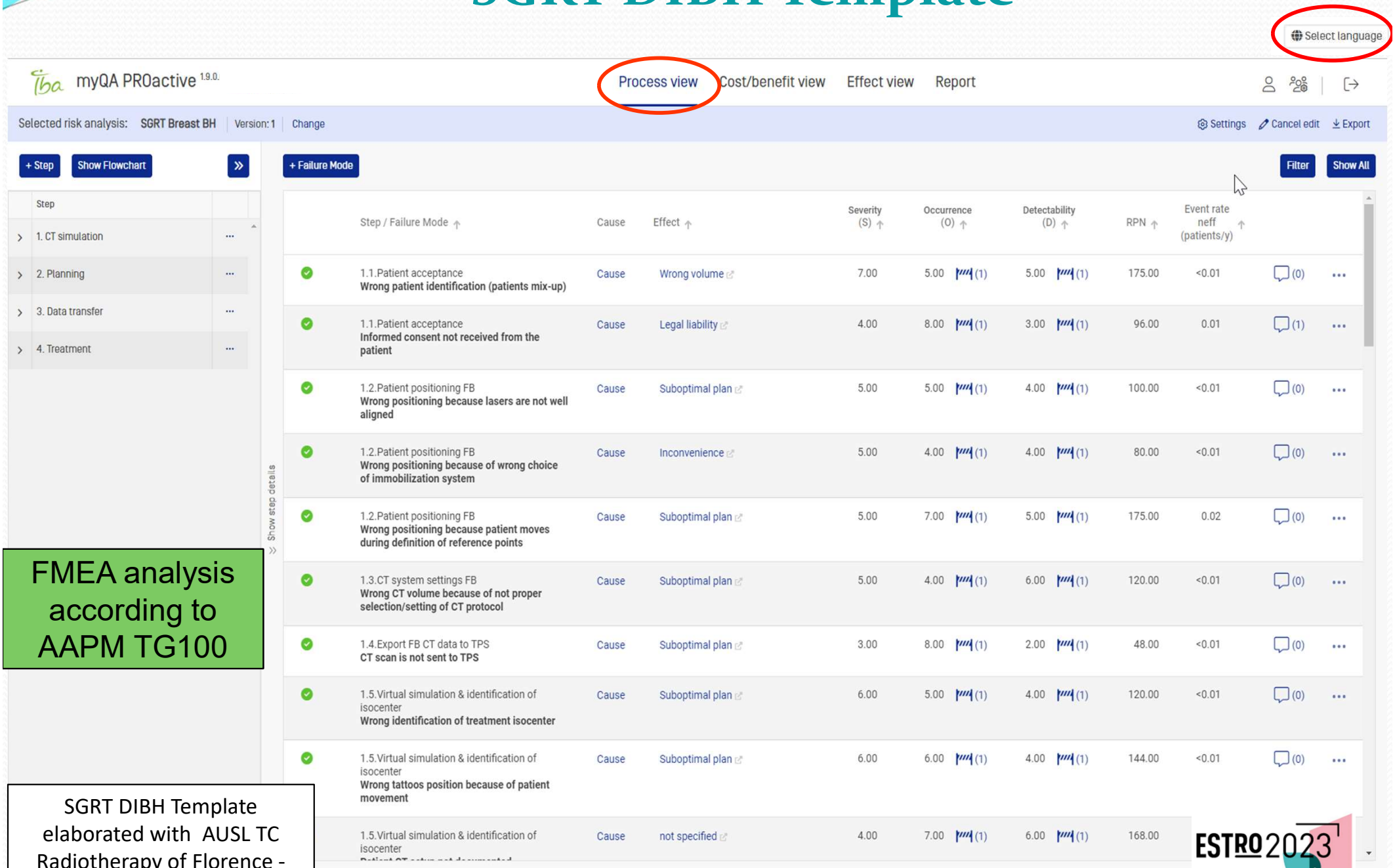
SGRT DIBH Template



FMEA analysis according to AAPM TG100

SGRT DIBH Template elaborated with AUSL TC Radiotherapy of Florence - Italy

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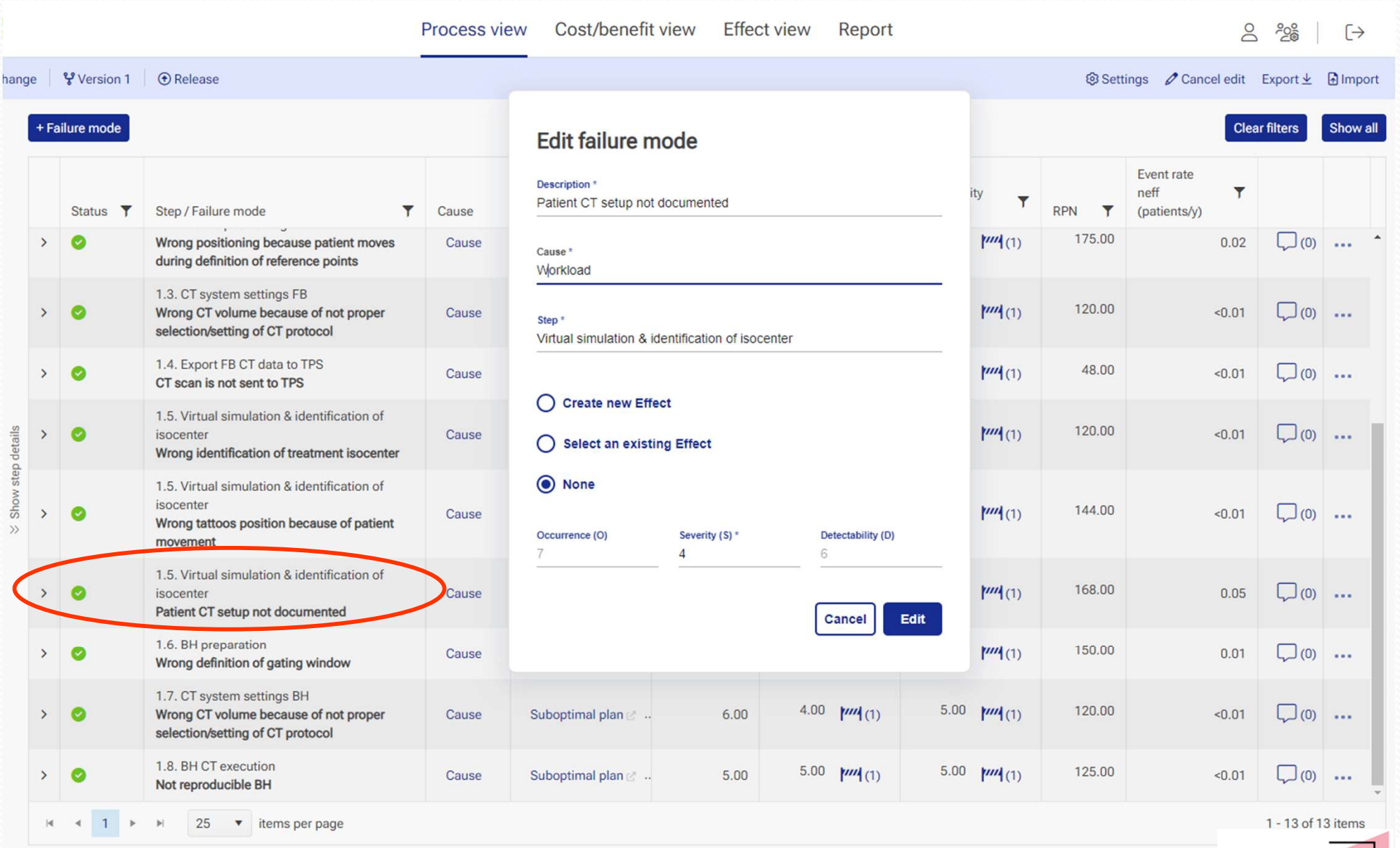
SGRT DIBH Template



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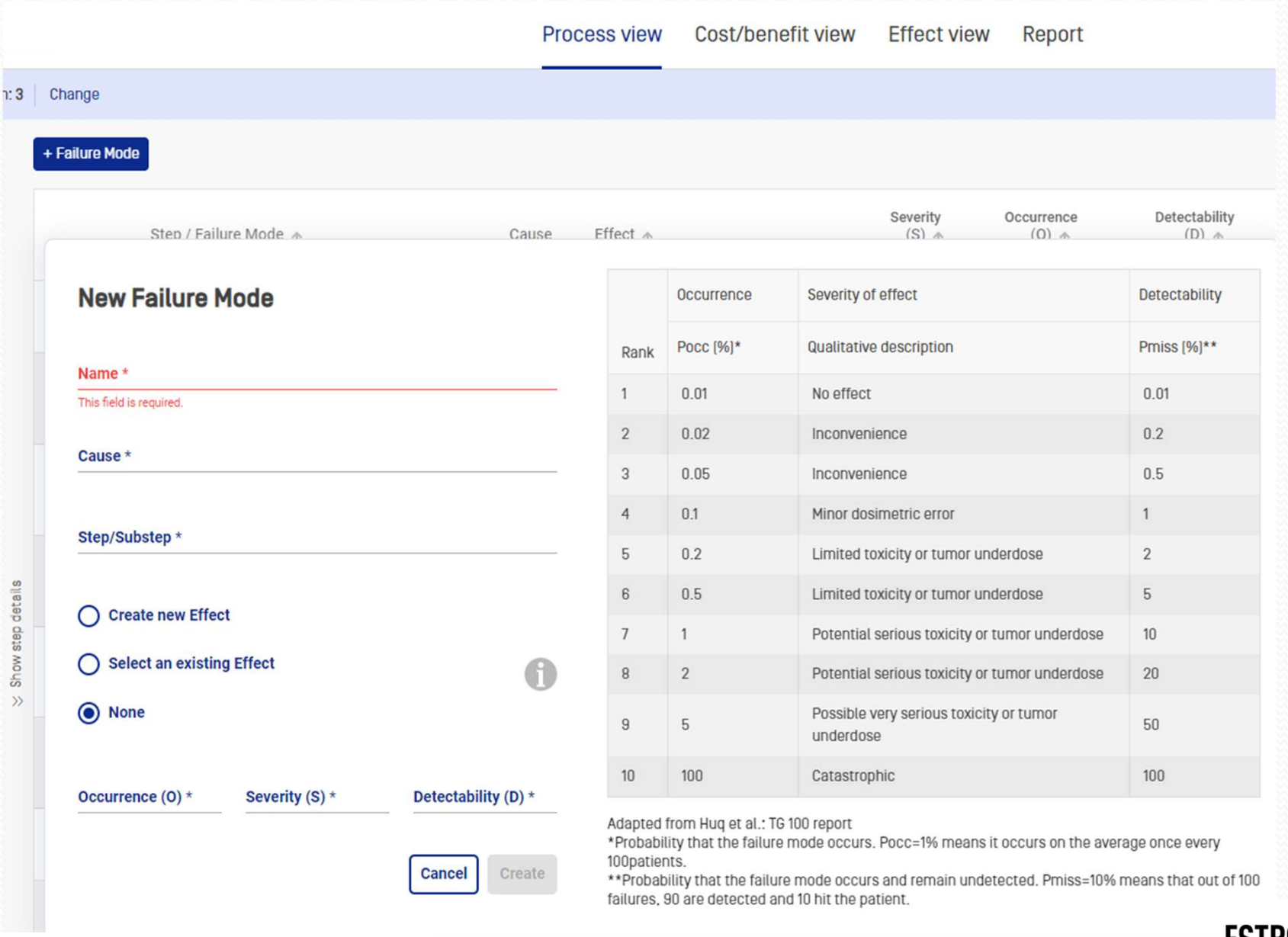
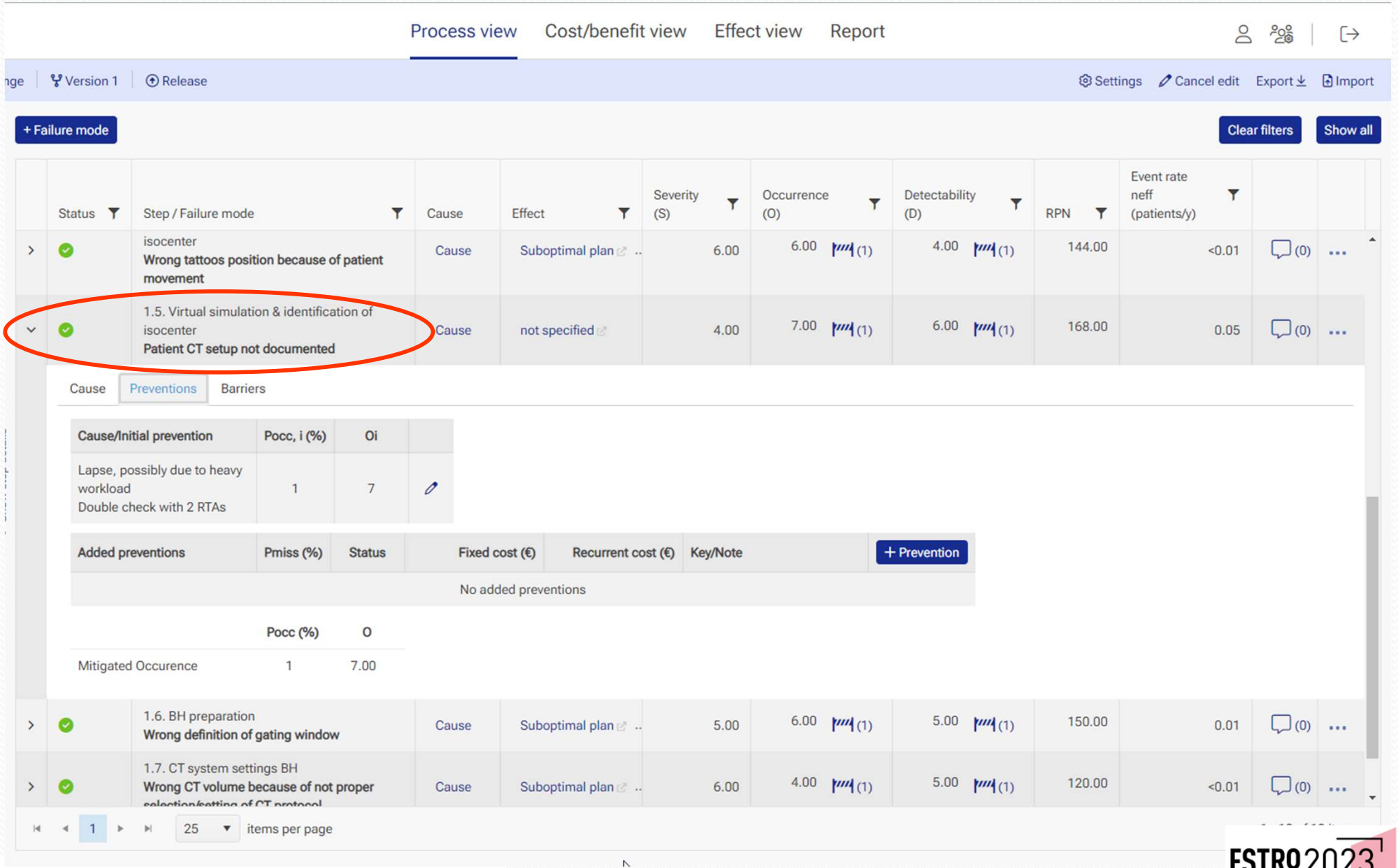
SGRT DIBH Template



	Occurrence	Severity of effect	Detectability
Rank	Pocc [%]*	Qualitative description	Pmiss [%]**
1	0.01	No effect	0.01
2	0.02	Inconvenience	0.2
3	0.05	Inconvenience	0.5
4	0.1	Minor dosimetric error	1
5	0.2	Limited toxicity or tumor underdose	2
6	0.5	Limited toxicity or tumor underdose	5
7	1	Potential serious toxicity or tumor underdose	10
8	2	Potential serious toxicity or tumor underdose	20
9	5	Possible very serious toxicity or tumor underdose	50
10	100	Catastrophic	100

Adapted from Huq et al.: TG 100 report
*Probability that the failure mode occurs. Pocc=1% means it occurs on the average once every 100patients.
**Probability that the failure mode occurs and remain undetected. Pmiss=10% means that out of 100 failures, 90 are detected and 10 hit the patient.

SGRT DIBH Template



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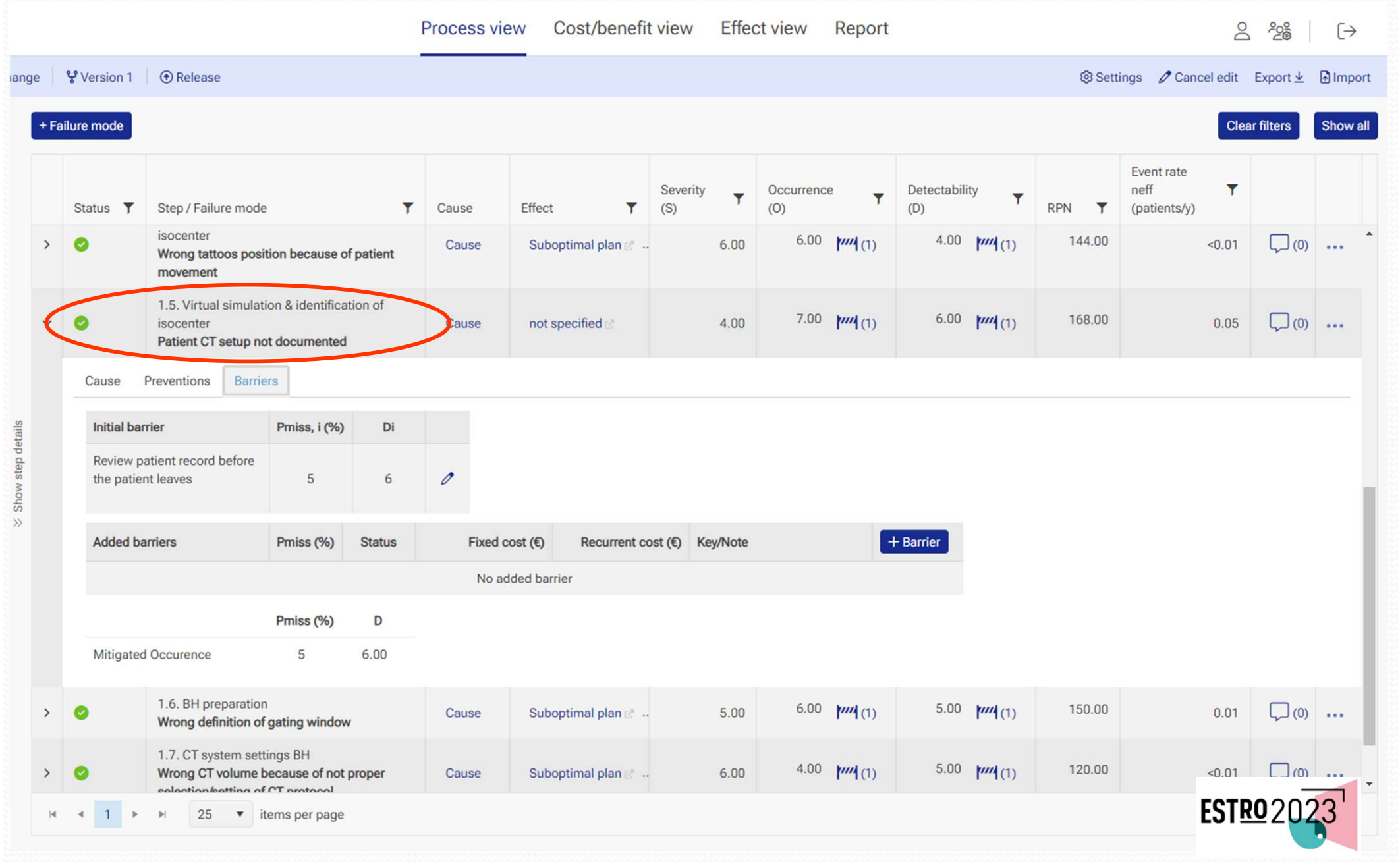
SGRT DIBH Template



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SGRT DIBH Dashboard

+ Step | Show flowchart

Step	Order steps	F (% of patients through the step)	R (step repetitions per patient)	Failure Modes Total	✓	!	✗	Event rate Neff (patients/y)	Note
1. CT simulation		100	1	13	13	0	0	0.12	
2. Planning		100	1	9	2	7	0	~~2.01~~ → 0.05	
3. Data transfer		100	1	17	~~17~~ → 1	0	0	~~0.05~~ → 0.04	
4. Treatment		100	1-20	9	8	1	0	0.06	

Expected event rate:
affected patients number per year is automatically evaluated

Npt/year x F x R x Pocc (O) x Pmiss (D)

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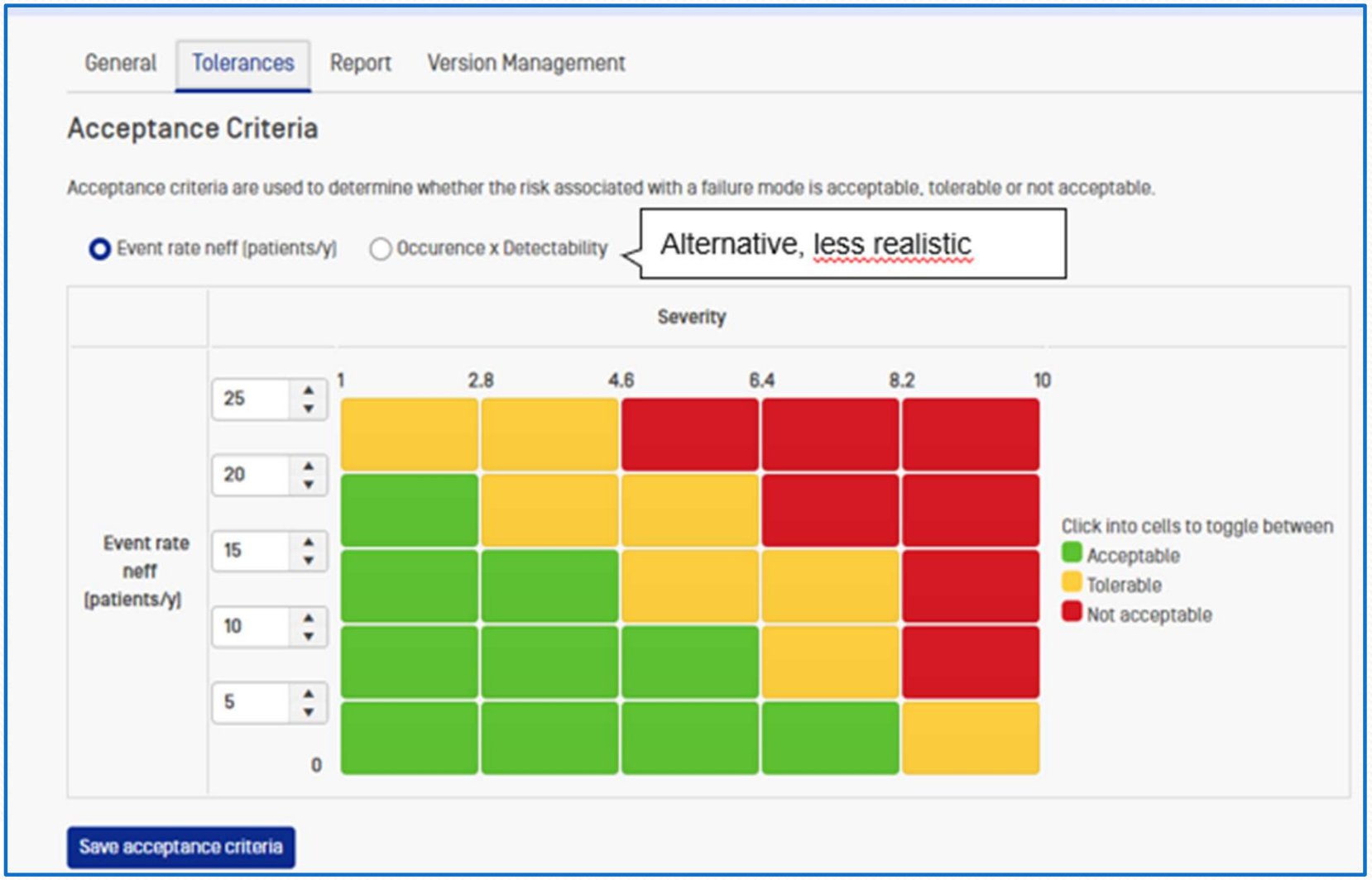
SGRT DIBH Risk matrix

- Set tolerances with a risk-matrix approach
- Tollerance based on: Event rate
  Occurrence and Detectability



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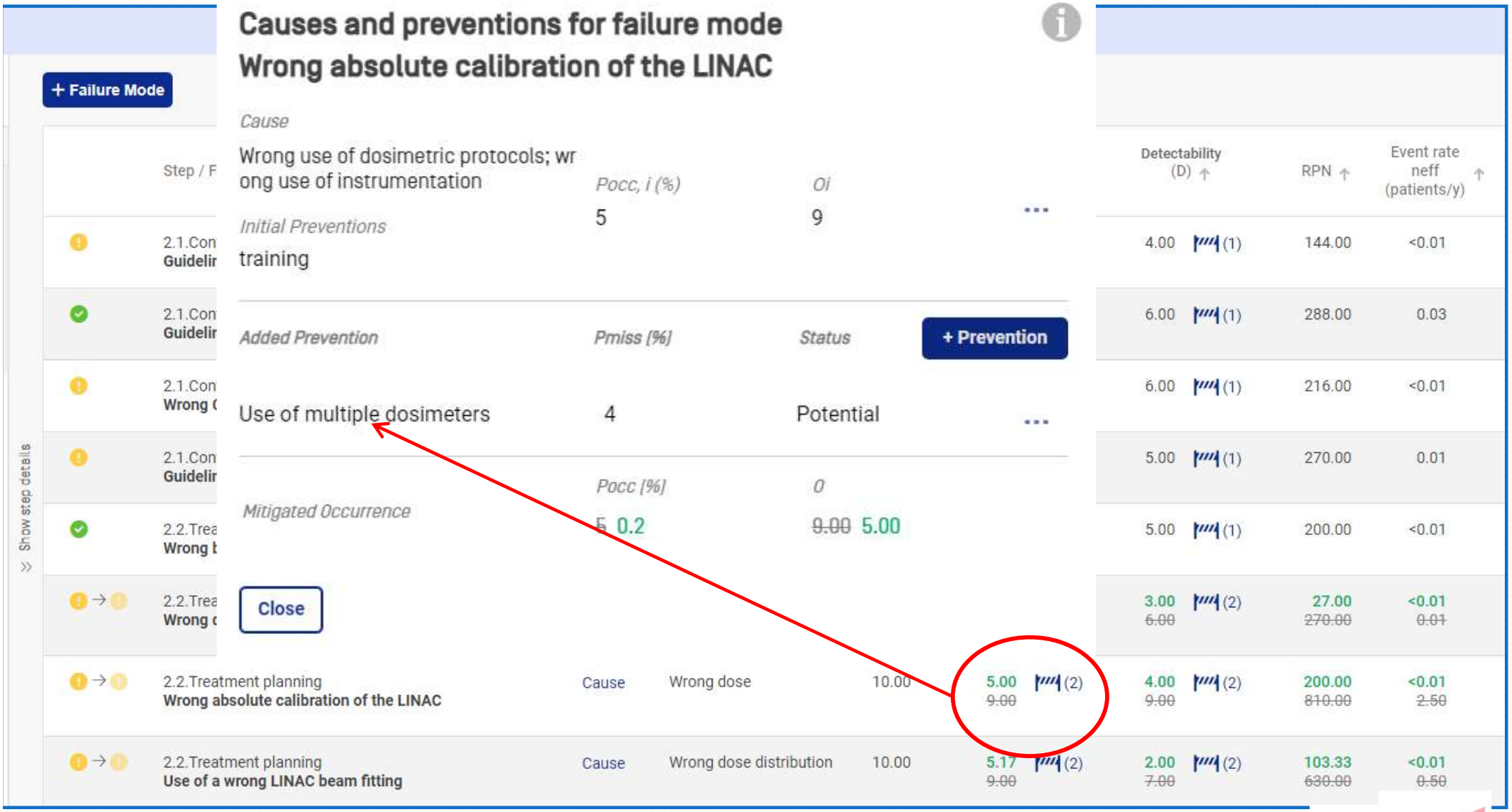
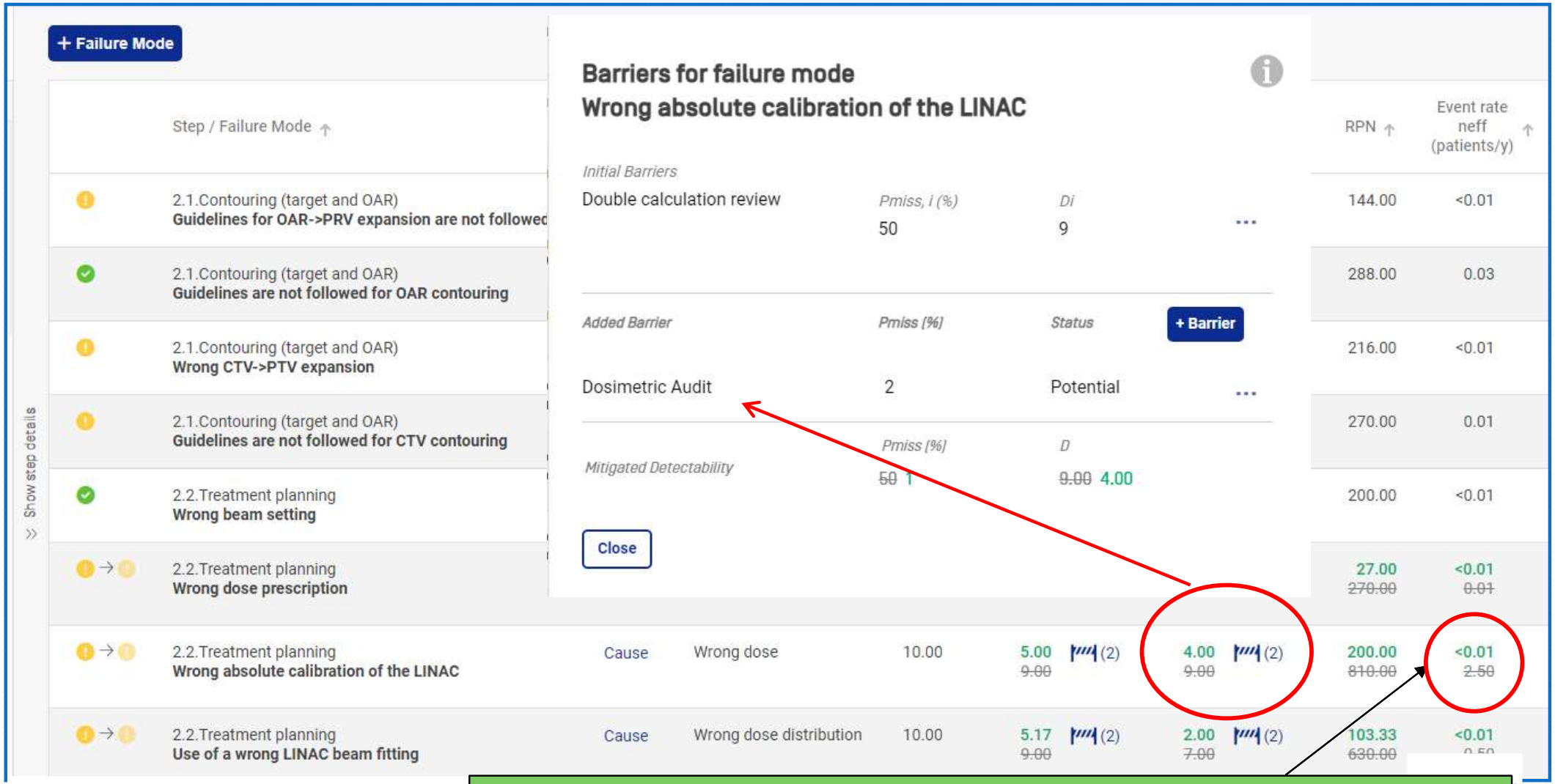
Definition of preventions



Definition of barriers



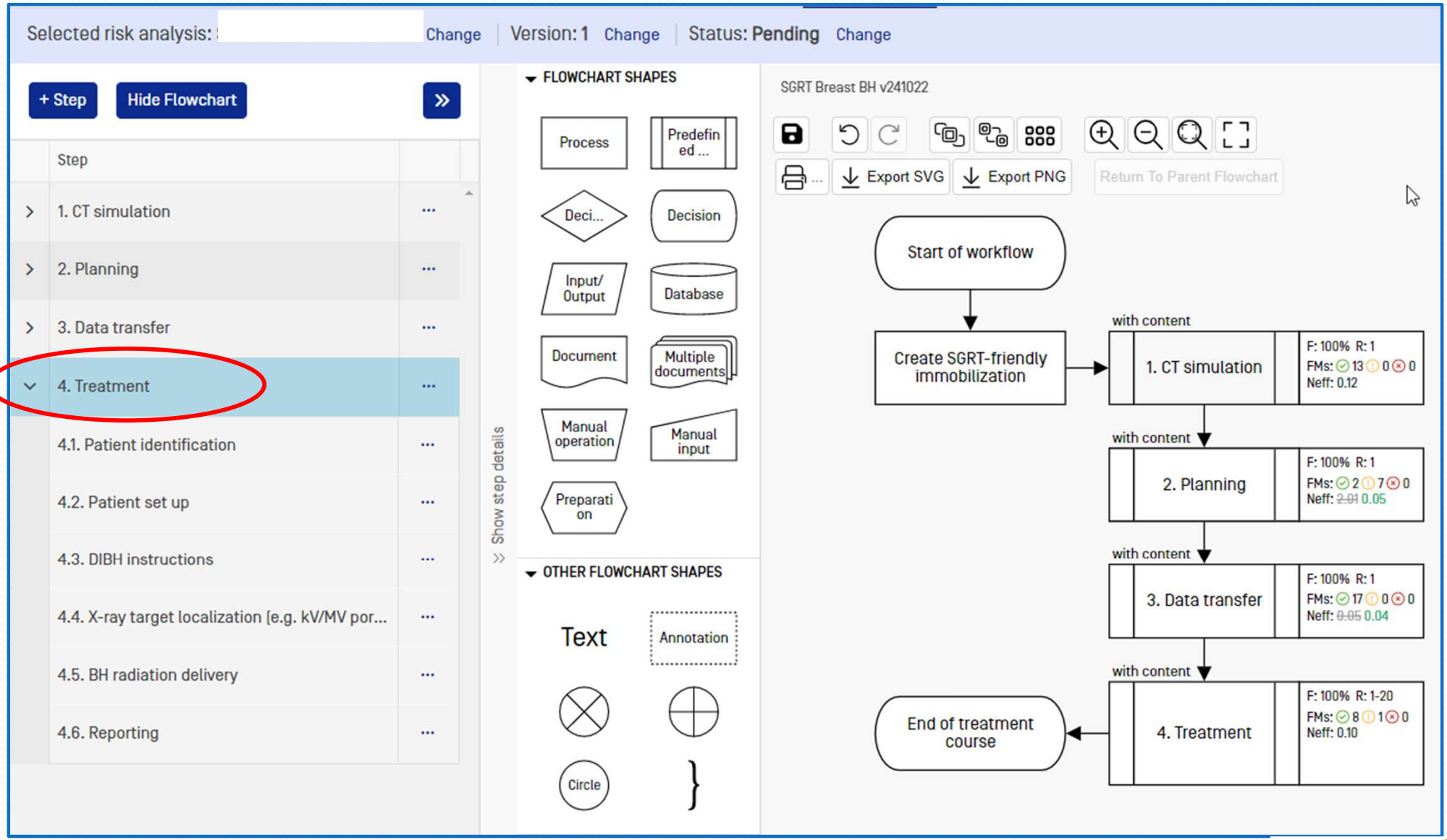
The SW automatically calculates the „benefit" of a mitigation: neff(with)-neff(wihtout)

Cost-benefit analysis of mitigation actions

Drag a column header and drop it here to group by that column

Context			Mitigations				Cost/Benefit			
Step	Failure Mode	Effect	Description	Type	Status	Pmiss	Benefit Δneff (patients/y)	Fixed cost (€)	Recurrent C((€)	Total @5y (€)
22. Treatment planning	Wrong absolute calibration of the LINAC	Wrong dose	Dosimetric Audit	Barrier	Potential	2.00 %	1.42	5,000	1,000	10,000
22. Treatment planning	Use of a wrong LINAC beam fitting	Wrong dose distribution	Dosimetric audit	Barrier	Potential	2.00 %	0.49	5,000	1,000	10,000
22. Treatment planning	Wrong dose prescription	Wrong dose	Verification of availability of printed dose prescription	Barrier	Potential	10.00 %	<0.01	1,000	1,000	6,000
22. Treatment planning	Wrong dose prescription	Wrong dose	Printed form to confirm dose prescription	Prevention	Potential	5.00 %	<0.01	1,000	1,000	6,000
22. Treatment planning	Use of a wrong LINAC beam fitting	Wrong dose distribution	pre-clinical dosimetric verifications	Prevention	Potential	5.00 %	0.48	100,000	8,000	140,000
22. Treatment planning	Wrong absolute calibration of the LINAC	Wrong dose	Use of multiple dosimeters	Prevention	Potential	4.00 %	1.39	10,000	1,000	15,000
31. Export/Import plan and body contours to SGRT system (FB)	Wrong definition of ROI (FB) in SGRT system	Inconvenience	Check settings before first fraction	Barrier	Potential	20.00 %	<0.01	1,000	1,000	6,000

SGRT DIBH Flowchart



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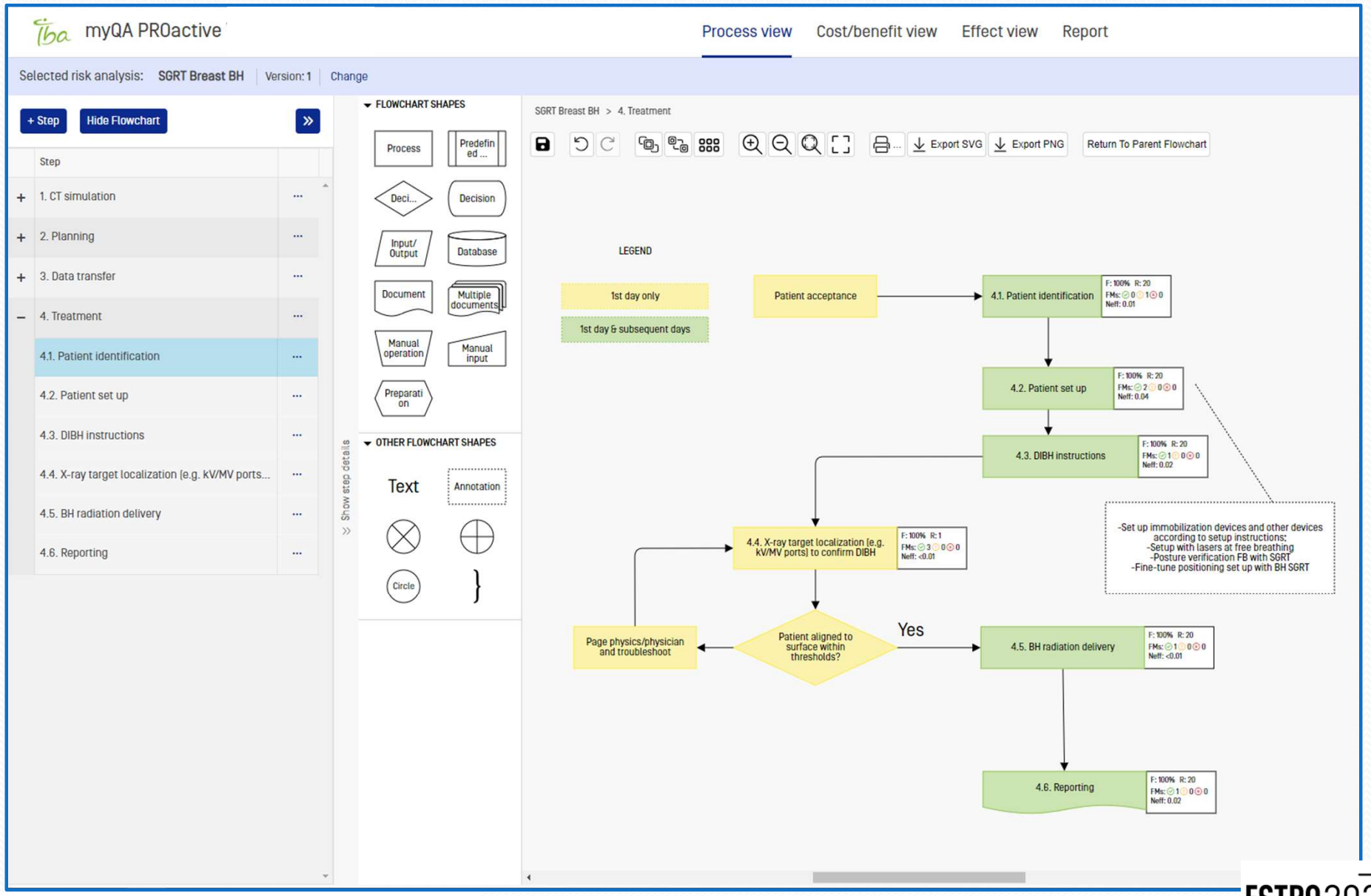
sub-Flowchart



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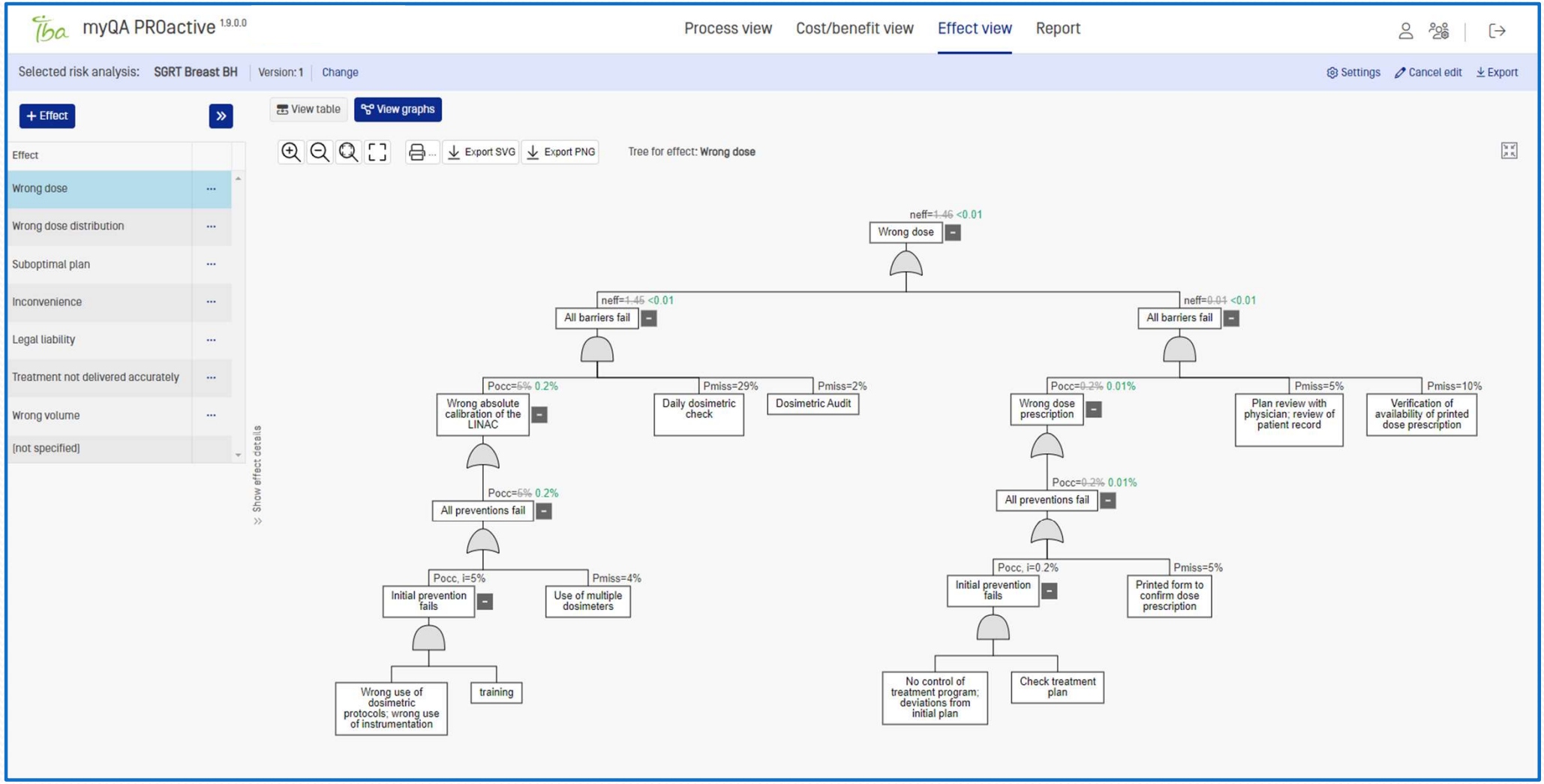
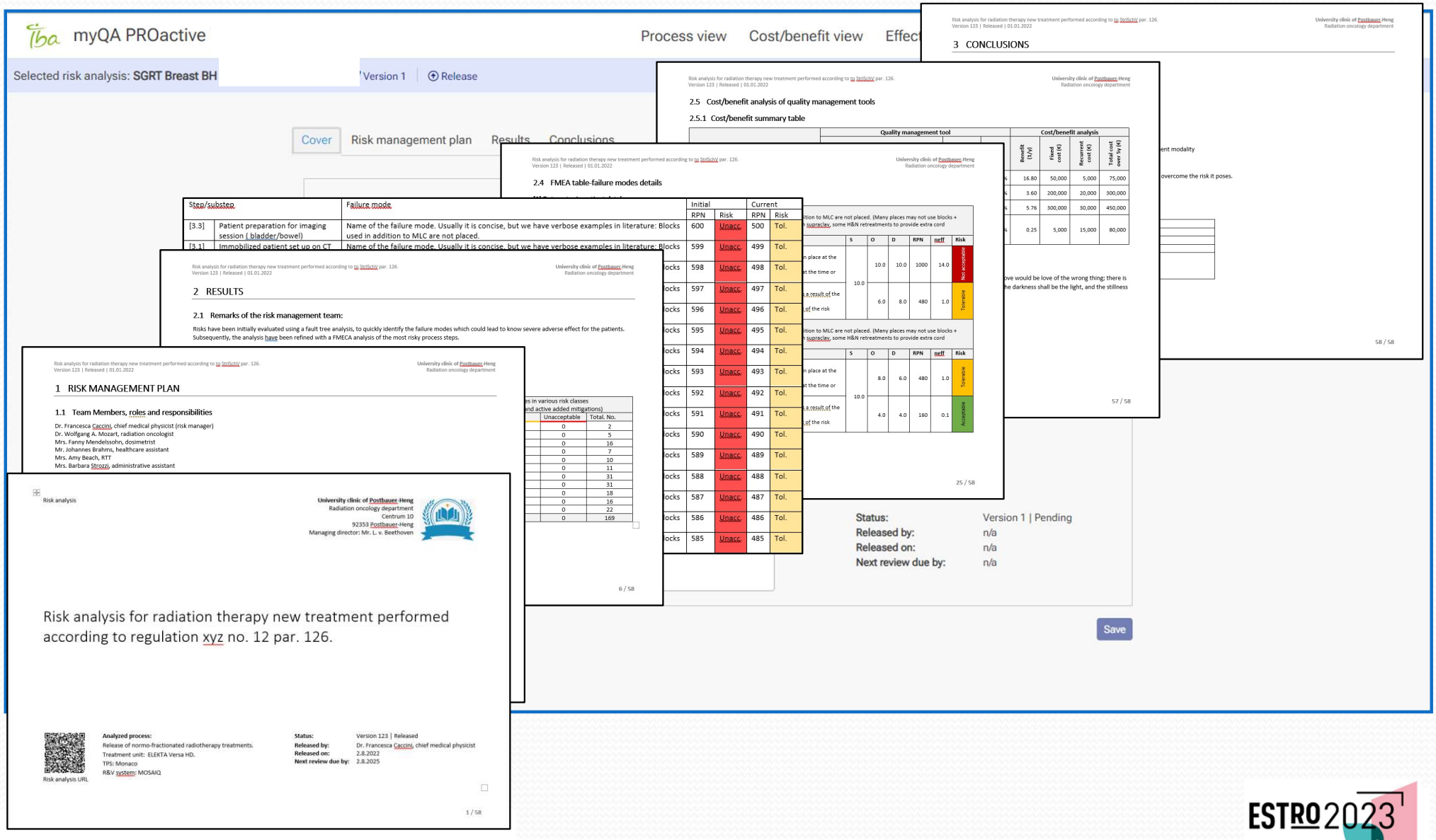
Fault Tree Analysis



Report Generation



Conclusions

myQA PROactive SW for risk management allows:

- Efficient FMEA analysis
- Agile FMEA analysis review
- Facilitates periodic updating of FMEA analysis
- Comparison of risk reduction measures through cost/benefit analyses
- Documentation of the risk analysis

THANKS FOR YOUR ATTENTION !!