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Pharmacovigilance of systemic antipsoriatic treatment: Results from more than 17,000 patient years in the German Psoriasis Registry PsoBest

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German Psoriasis Registry PsoBest

- Non-interventional, multicenter patient registry
- Adult patients with moderate to severe psoriasis
- Observation regardless of further treatment course



initiated 2008



~ 550 registry sites



~ 14,000 patients



10- 15 years observation

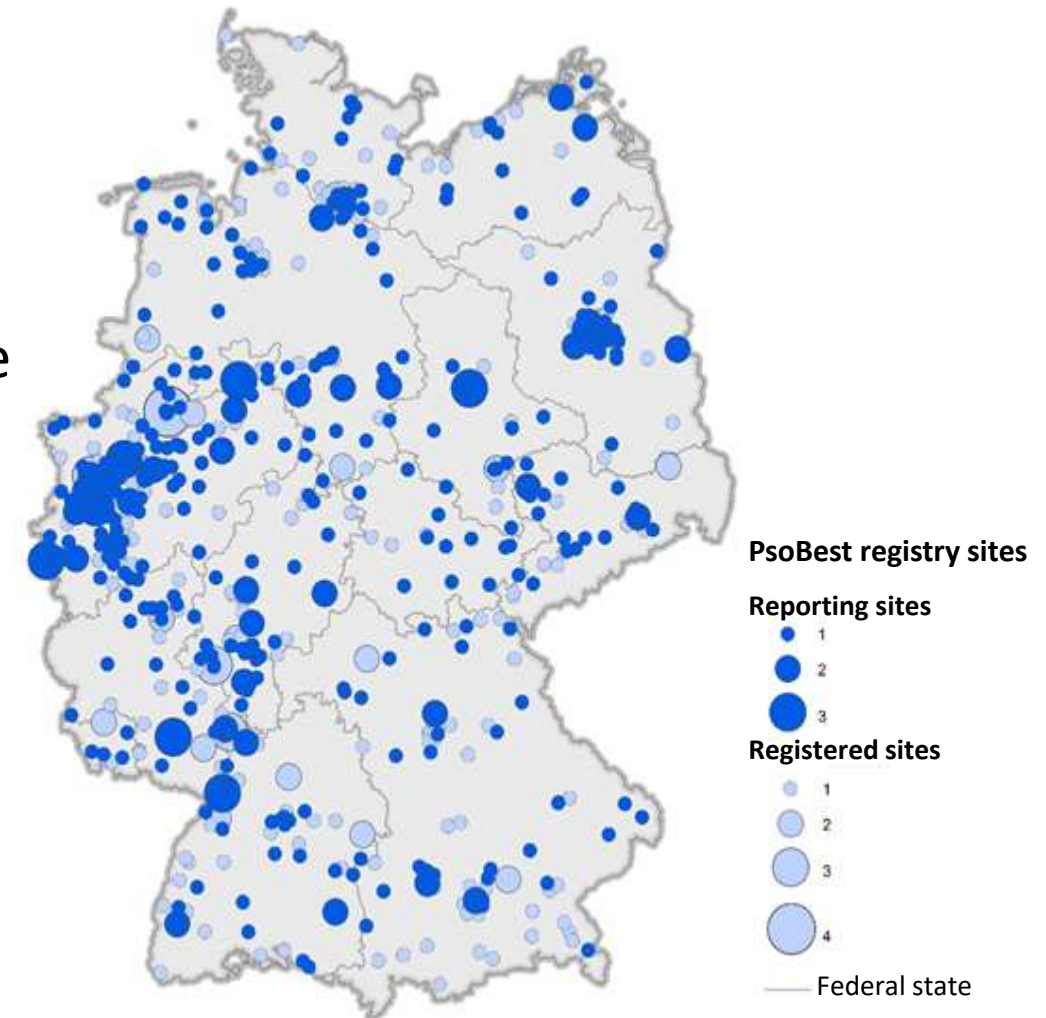


Figure: Number of registry sites per post code area throughout Germany

Event assessment and assignment

Non-serious adverse events

- Without inpatient hospitalisation
- Documentation via regular visit
- e.g. new comorbidity, injuries



serious adverse events

- With inpatient hospitalisation
- Documentation via special form and rapid report
- e.g. MI, malignancies, death



Tx A

Tx C

Tx B



Tx A



Tx B

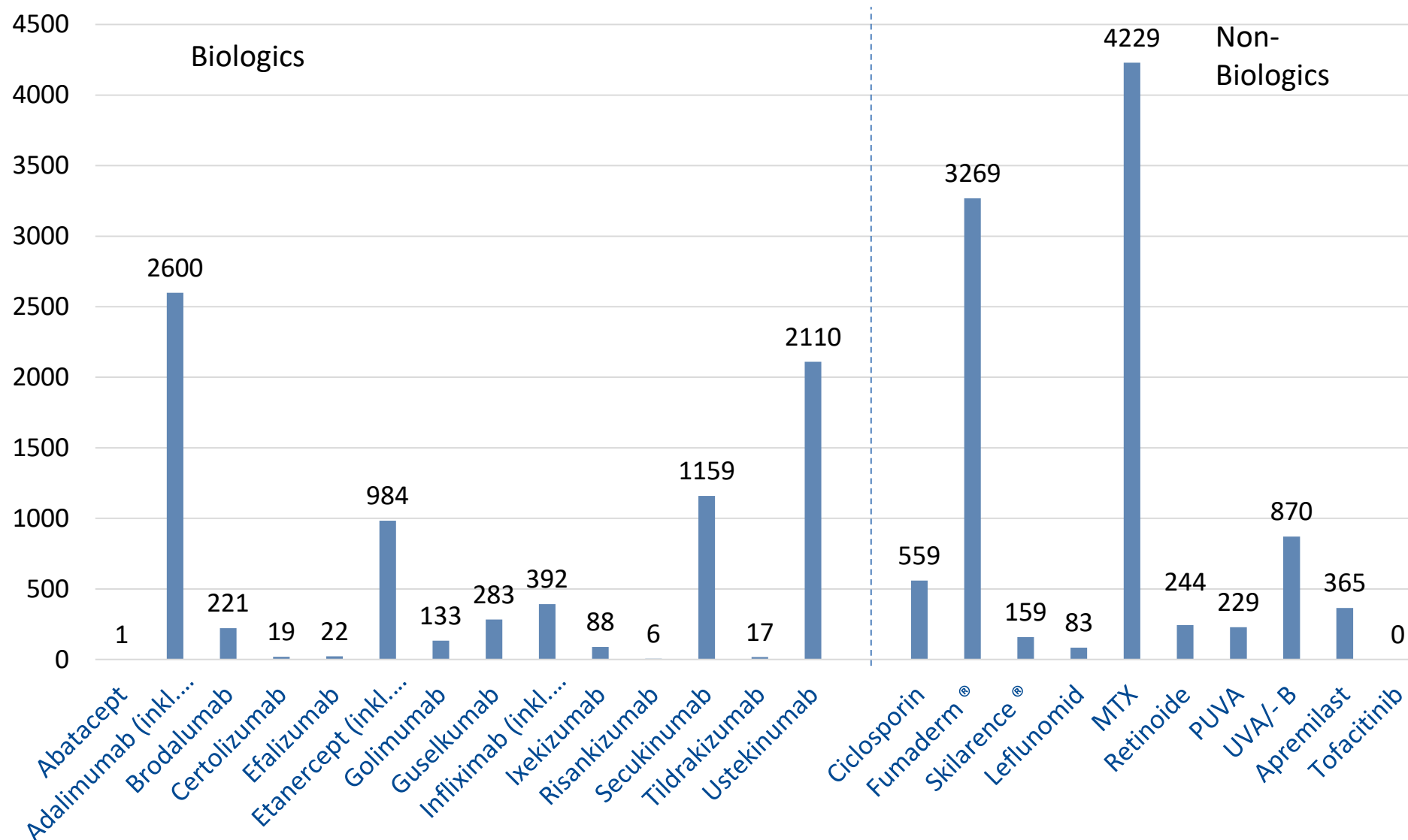


Tx A

Tx B

Tx C

time



9,748 patients

7,854 years biologics

58 years biosimilars

9,158 years non-biologics

Figure: Prospective exposure time in PsoBest, n= 9,748

Cumulative data from 12-13-2007 to 12-31-2019

Patient Baseline

Biologics, n= 3,888	n	mean	median	range
Age [years]	3,888	47.7	48.0	18 - 89
Duration of illness [years]	3,552	20.1	18.0	0 - 70
PASI	3,796	16.1	14.1	0 - 66.6
DLQI	3,704	12.4	12.0	0 - 30
BMI	3,837	29.0	28.1	14.9 - 57.9
Non-biologics, n= 6,251	n	mean	median	range
Age [years]	6,251	47.6	48.0	18 - 92
Duration of illness [years]	5,688	16.2	13.0	0 - 76
PASI	6,108	14.4	12.5	0 - 69.6
DLQI	5,957	11.2	11.0	0 - 30
BMI	6,188	28.4	27.5	14.7 - 67.3

61.4 % male

54.2 % nail psoriasis

41.5 % psoriatic arthrtis

57.3 % male

46.1 % nail psoriasis

26.4 % psoriatic arthrtis

Combined treatment possible; **P**soriasis **A**rea and **S**everity **I**ndex 0= no to 72= maximum severity,
Body **S**urface **A**rea 0 to 100 %, **D**ermatology **L**ife **Q**uality **I**ndex 0= no to 30= maximum impairment

Non-serious adverse events in non-biologic treatment










Rank	System organ class	events	patients	% patients	Patient rate*
1	Gastrointestinal disorders	1950	1079	17.26	11.80 (11.10-12.52)
2	General disorders and administration site conditions	1296	930	14.88	10.17 (9.52-10.84)
3	Skin and subcutaneous tissue disorders	630	457	7.31	5.00 (4.55-5.48)
4	Infections and infestations	667	456	7.29	4.98 (4.54-5.46)
5	Investigations	465	335	5.36	3.66 (3.28-4.08)
6	Nervous system disorders	339	262	4.19	2.86 (2.53-3.23)
7	Musculoskeletal and connective tissue disorders	311	242	3.87	2.65 (2.32-3.00)
8	Blood and lymphatic system disorders	295	214	3.42	2.34 (2.04-2.67)
9	Vascular disorders	215	187	2.99	2.04 (1.76-2.36)
10	Psychiatric disorders	165	134	2.14	1.46 (1.23-1.73)
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* Patients cumulative/100 Patient Years (95% confidence interval), as-exposed analysis



Non-serious adverse events in biologic treatment

Rank	System organ class	events	patients	% patients	Patient rate*
1	General disorders and administration site conditions	1048	724	18.62	9.22 (8.56-9.91)
2	 Infections and infestations	898	539	13.86	6.86 (6.30-7.47)
3	Musculoskeletal and connective tissue disorders	332	248	6.38	3.16 (2.78-3.58)
4	 Gastrointestinal disorders	297	207	5.32	2.64 (2.29-3.02)
5	 Skin and subcutaneous tissue disorders	252	194	4.99	2.47 (2.13-2.84)
6	 Investigations	197	153	3.93	1.95 (1.65-2.28)
7	 Nervous system disorders	159	128	3.29	1.63 (1.36-1.94)
8	Respiratory, thoracic and mediastinal disorders	154	124	3.19	1.58 (1.31-1.88)
9	 Vascular disorders	116	105	2.70	1.34 (1.09-1.62)
10	Psychiatric disorders	108	90	2.31	1.15 (0.92-1.41)
...					
16	 Blood and lymphatic system disorders	41	35	0.90	0.45 (0.31-0.62)
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* Patients cumulative/100 Patient Years
(95% confidence interval), as-exposed analysis

Significantly higher  patient rate compared to non-biologics
lower 

Serious adverse events

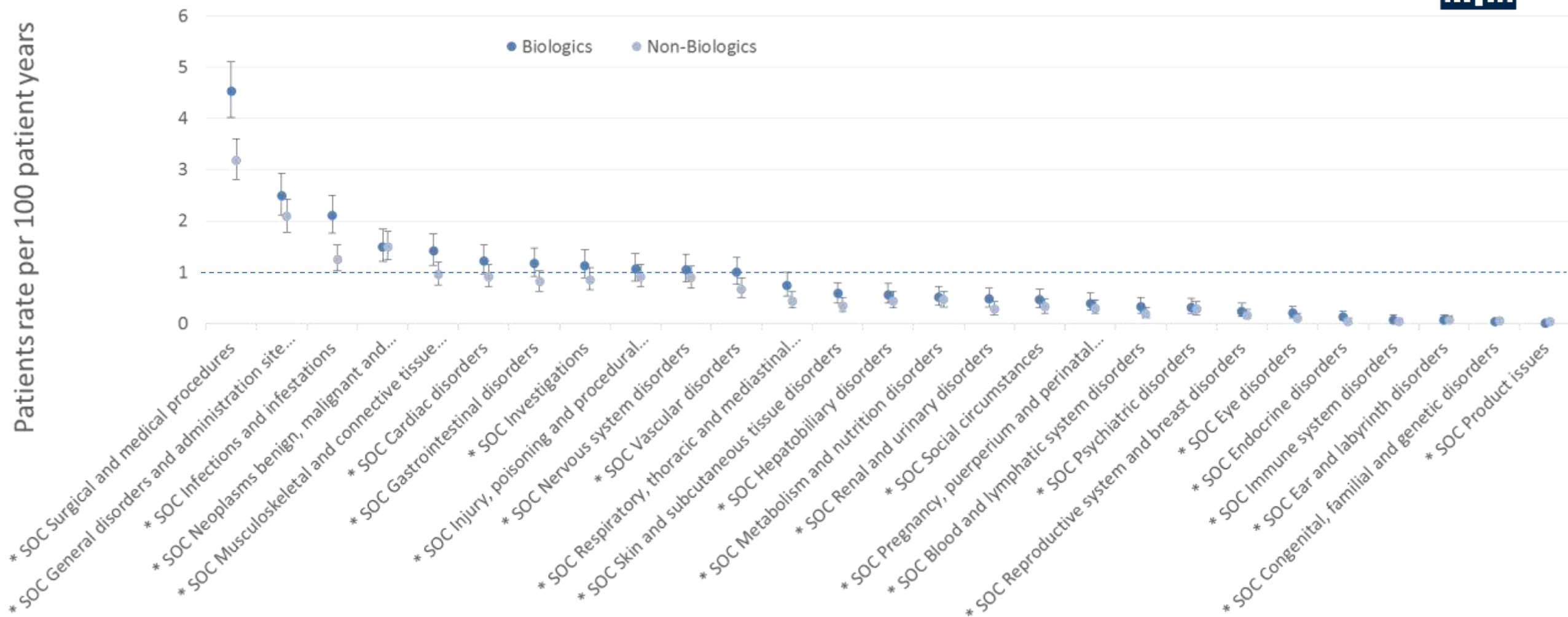


Figure: Standardized patient rates per 100 patient years exposed to biologics and non-biologics (as-exposed analysis)

All-cause death and malignancies



Biologics

	All cause death	Malignancies
male	0.57 (0.38-0.83)	0.93 (0.68-1.25)
female	0.51 (0.28-0.86)	1.25 (0.87-1.75)
total	0.55 (0.40-0.75)	1.05 (0.83-1.31)

Non-Biologics

	All cause death	Malignancies
male	0.83 (0.61-1.11)	1.02 (0.77-1.32)
female	0.45 (0.26-0.72)	1.21 (0.89-1.62)
total	0.67 (0.52-0.86)	1.10 (0.89-1.33)

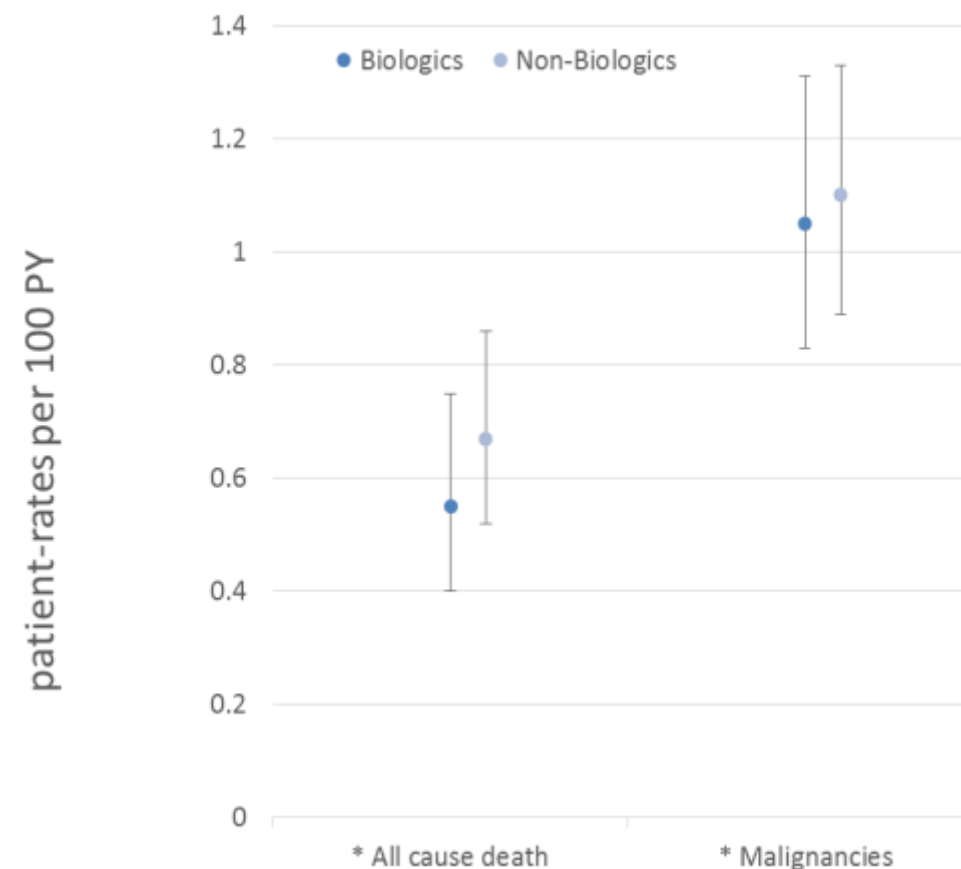


Figure: Standardized patient rates per 100 patient years ever exposed to biologics and non-biologics (ever-exposed analysis)

Conclusions

- Specific differences in non-serious adverse events, predominantly well known
- differences in serious adverse events < 1 patient/100 patient years
- Registry data shows the high safety of systemic psoriasis therapy in Germany





Visit us!

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