Clinical CRC registries of the Czech Society for Oncology

Why do we have problems with equity and early access to the innovative CRC therapy?

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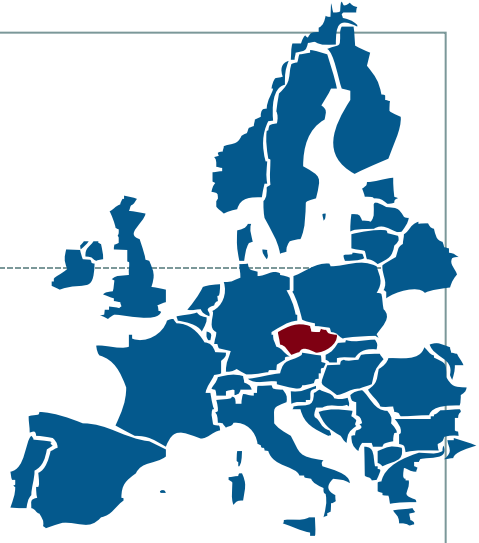


Early access to the right therapy is also a kind of prevention

Inputs: CRC reality

Consequence of lack of screening: increasing usage of expensive care

Czech reality: predicted epidemiology of CRC in 2013

INCIDENCE (2013)

C18-C20	2013: predicted values	
	Incidence	(90% IS)
Stage I	**1 980**	(1 808; 2 150)
Stage II	**1 939**	(1 797; 2 081)
Stage III	**2 222**	(2 070; 2 373)
Stage IV	**2 177**	(2 022; 2 332)
Stage unknowen – objective reasons	**360**	(237; 483)
Stage not recorded	**86**	(56; 115)
TOTAL	**8 764**	(7 990; 9 534)

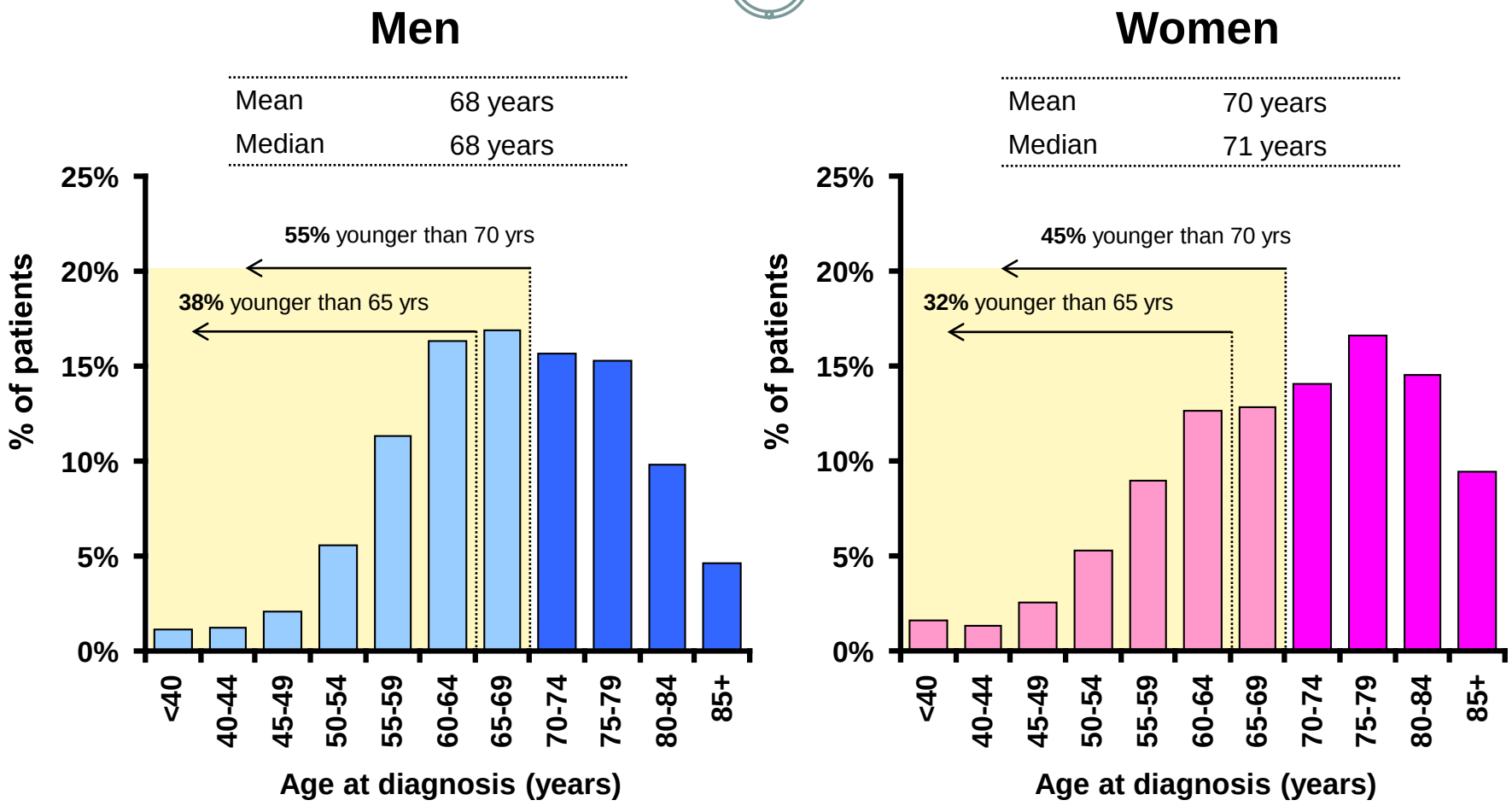
PREVALENCE (2013

C18-C20	2013: predicted values	
	Prevalence	(90% IS)
Stage I	**18 152**	(17 843; 18 461)
Stage II	**16 643**	(16 356; 16 930)
Stage III	**12 237**	(11 986; 12 488)
Stage IV	**7 557**	(7 361; 7 753)
Stage not recorded	**2 661**	(2 543; 2 779)
TOTAL	**57 250**	(56 089; 58 411)

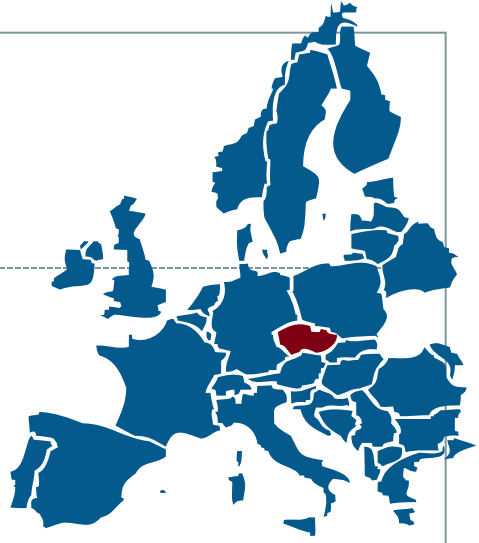
Based on the National Cancer Registry we are able to predict epidemiological and therapeutic burden. It is apparent that high incidence of CRC is driven mainly by late clinical stages, which form also substantial part of the CRC prevalence pool. High cost for this failure in early diagnostics is inevitable.

CRC cancer patients in demographic typology: age structure

2006 - 2010



Many CRC patients are relatively young, with significant life expectancy.



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Method

How to get real life data to optimize the care for CRC patients in practice?

Solution: information system based on representative clinical registries

The Czech project collects **fully representative data on the therapy** of CRC diagnosed in advanced clinical stage. The electronic data capture system works over **the Network of the Czech Comprehensive Cancer Centers**, which are responsible for the targeted therapy.

The principal aims are:

1. To identify risk factors leading to late diagnosis in different regions

2. To quantify access to the therapy and reach degree of equity of care

3. To ensure relevant application of the innovative therapy

4. To measure quality and outcomes of the care

Functional registries are based on complex data model

1. No. treated patients
2. Responsible hospitals, migration of patients

3. Typology 1. – demography – sex, age, region, ….
4. Typology 2. – diagnosis, diagnostic markers
5. Typology 3. – specific diagnostic markers, BMI, PS, …

6. Baseline therapy monitoring – time, dosage, administration, ….
7. Hospital stay – time, type
8. Monitoring of selected supportive therapy
9. Clinical reasoning of changes, interruptions, problems

10. Safety measures: adverse events, toxicity, grading, …..

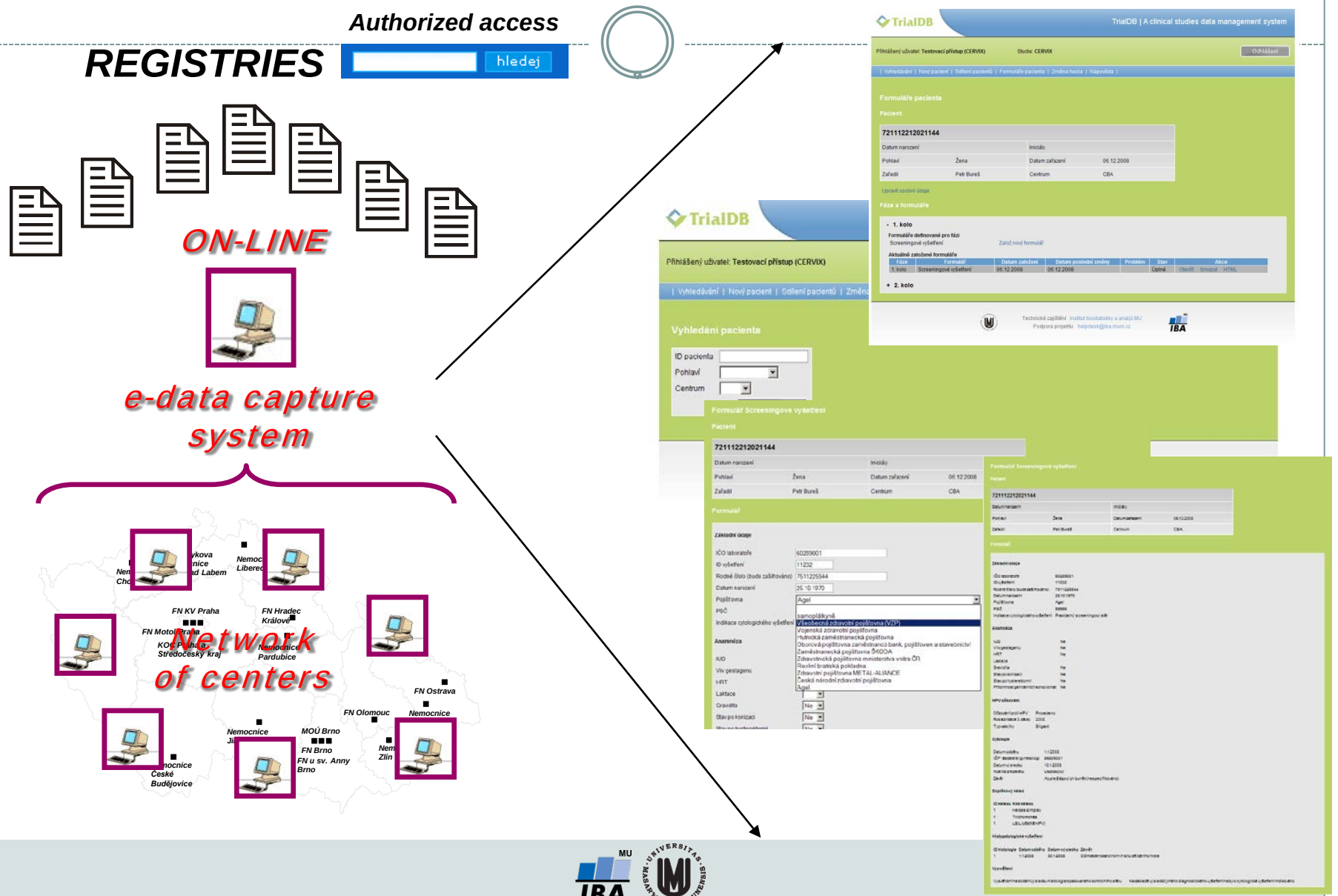
11. Outcome measures : therapeutic response, time-to-event statistics (e.g. DFS, PFS, DFI, OS), ….QL, ….

Administrative data = hospital support

+

Special data collection = registry

The system works over feasible on-line technology

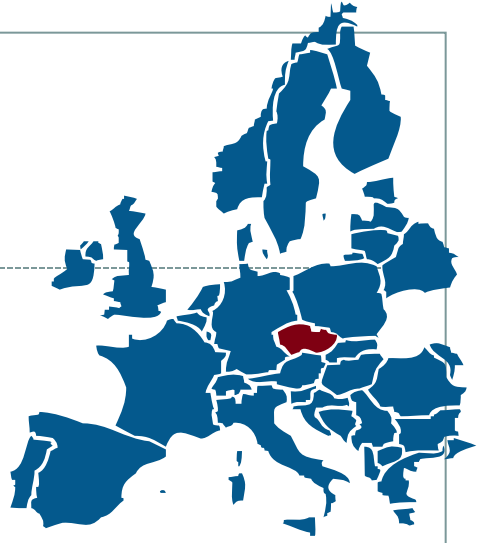


Example of data-base content: size of the registries focused on targeted therapy of advanced CRC

	No. of records of drug administration
CORECT registry *- colorectal carcinoma*	*6624*
BREAST registry *- breast carcinoma*	*4659*
TULUNG registry *- non-small cell lung carcinoma*	*4296*
RenIS registry *- renal cell carcinoma*	*3249*
Alimta registry *- mesothelioma*	*171*

In total more than 18 000 valid records

Data from March 2013



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Outcomes

Example: target therapy of CRC

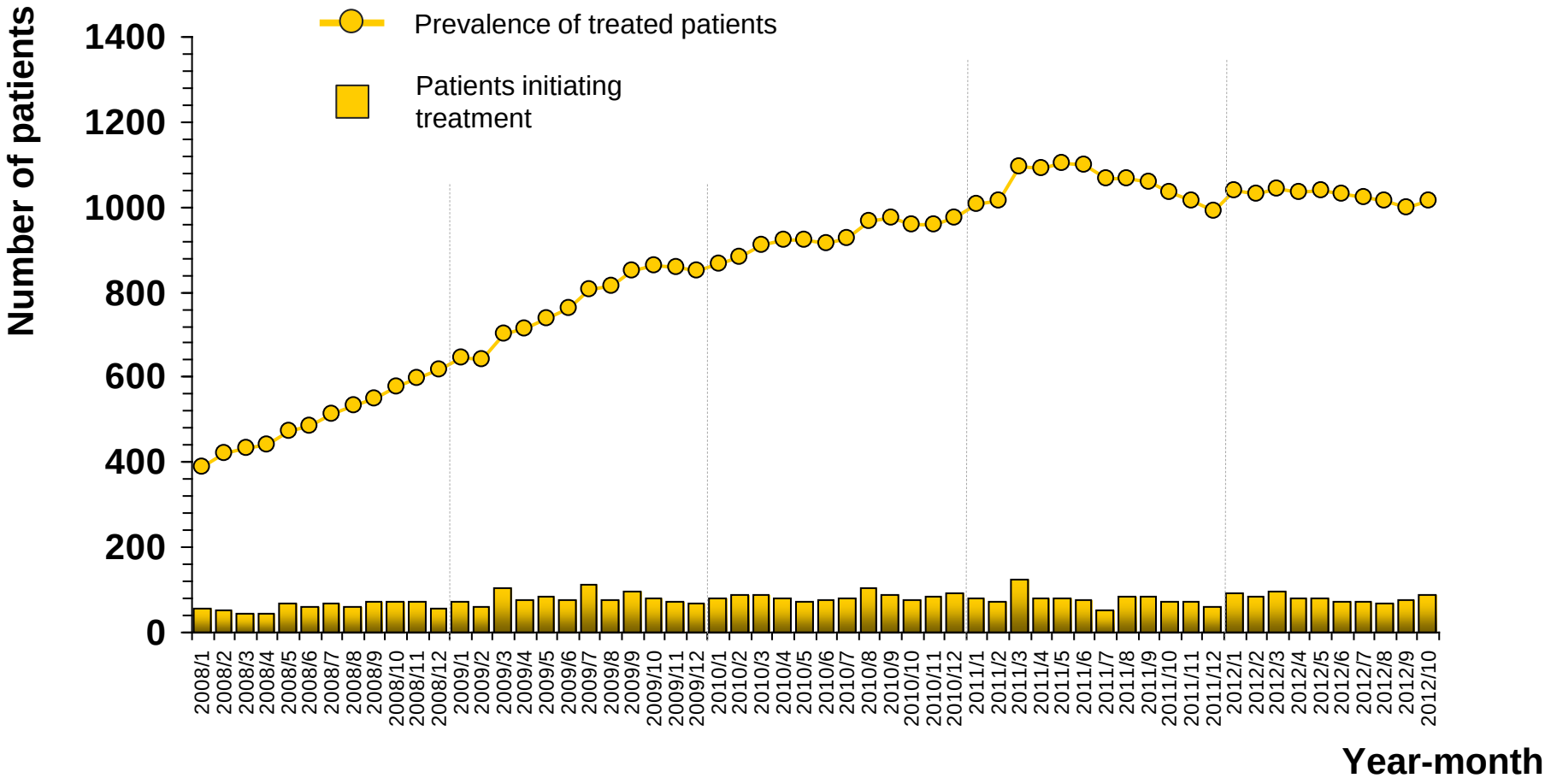
Targeted therapy as model segment of care for advanced CRC

Example: data structure allows to monitor long-term follow-up, including consecutive lines of treatment

Data source	Therapy	1. line	2. line	3. line	Other lines	Total
Corect-registry	**Avastin**	4312	426	82	35	4855
	Erbitux	193	514	444	94	1245
	Vectibix	32	156	274	62	524

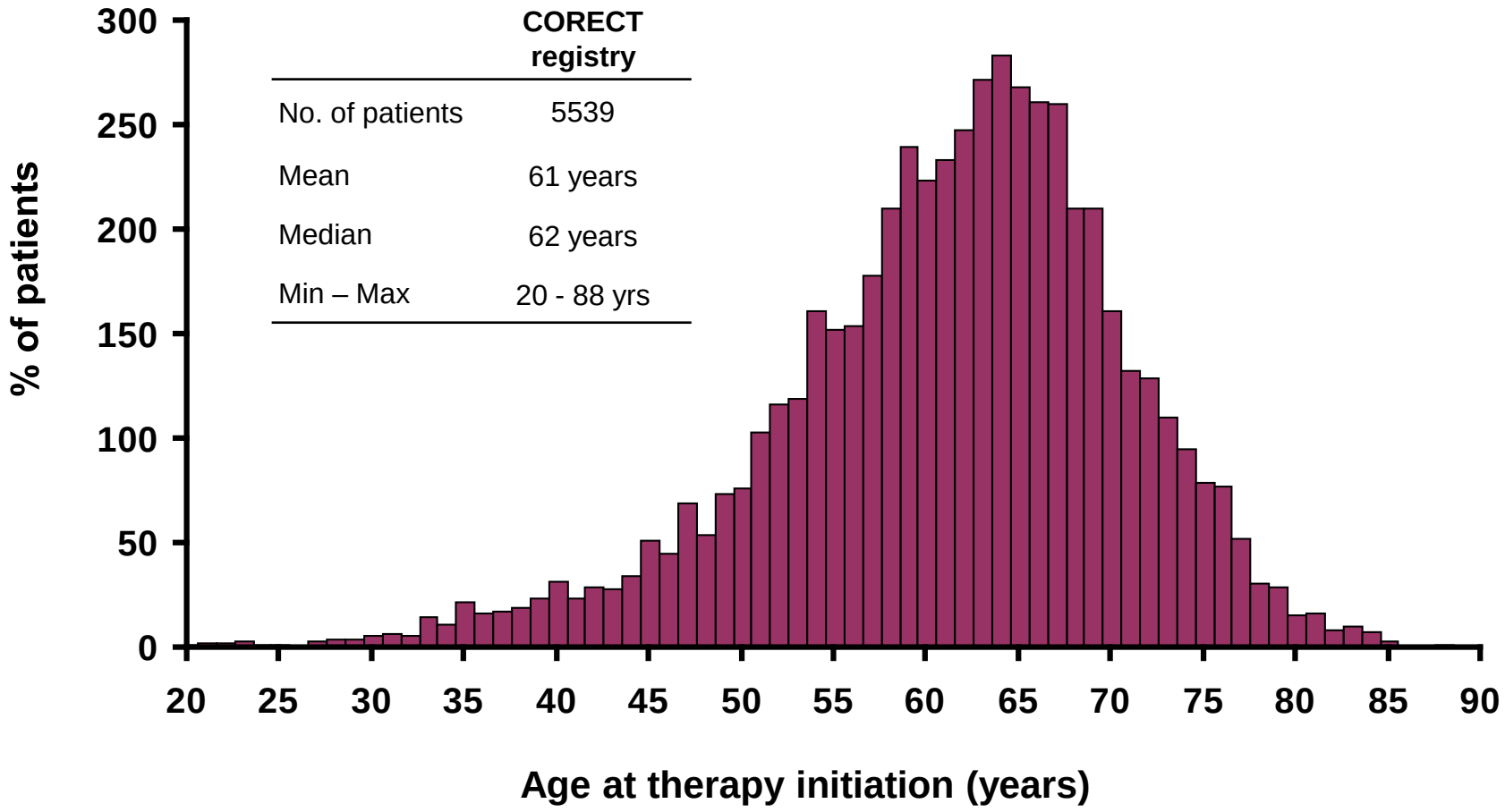
Data from March 2013

CORECT registry: Incidence and prevalence of treated patients (target therapy of advanced disease)



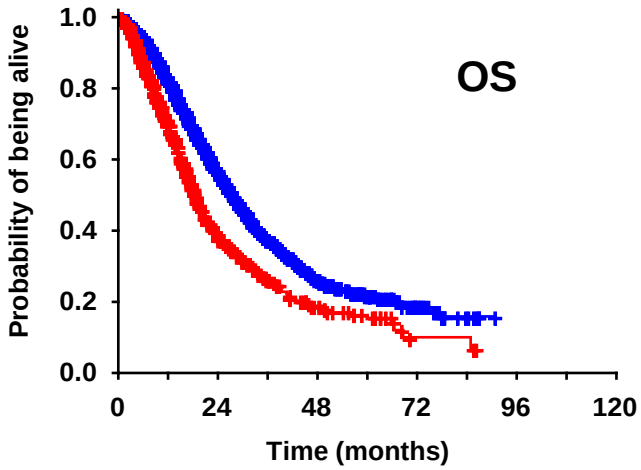
CORECT registry: Age of patients at time of therapy onset

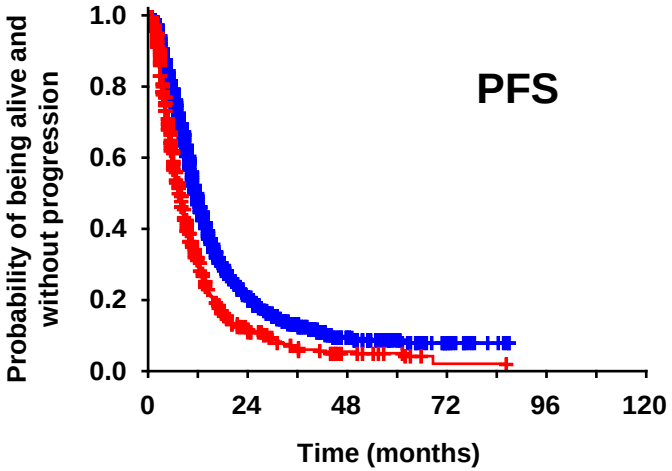
	CORECT registry
No. of patients	5539
Mean	61 years
Median	62 years
Min – Max	20 - 88 yrs



Data from March 2013

CORECT registry: Example of evaluation of outcomes





Line of treatment	N	Median OS (95% CI)	Median PFS (95% CI)
1. line	4531	27.2 months (26.1; 28.3)	11.2 months (10.8; 11.6)
2. line	1091	18.4 months (1.1; 19.6)	7.3 months (6.7; 7.9)

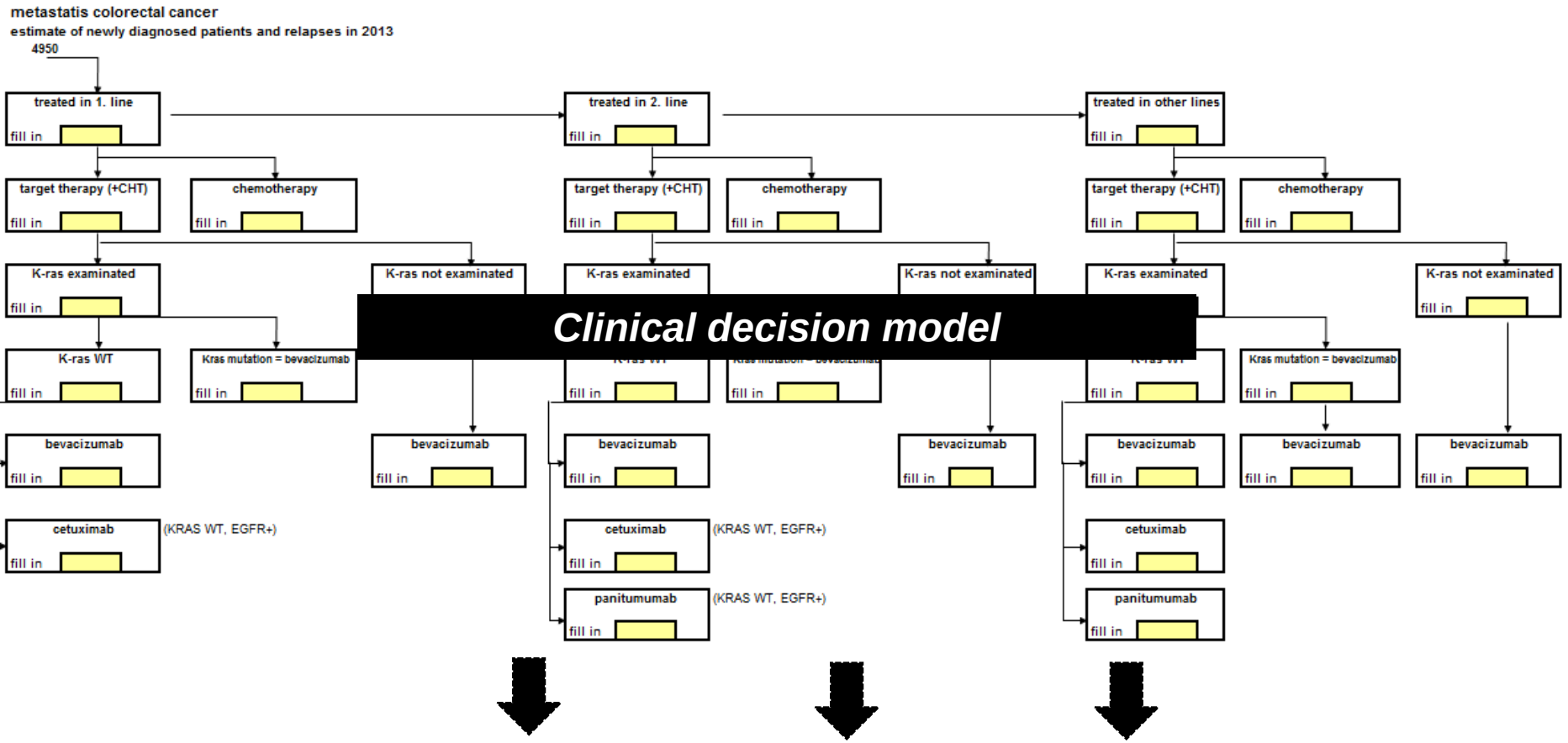
Benchmarking of reached survival

Data source	Drug and line of treatment	Median OS	Median PFS
CORECT registry	Avastin - 1. line	27,4 monhs	11.3 months
AVF2107g[1]	Avastin - 1. line	20.3 months	10.6 months
NO16966[2]	Avastin - 1. line	21.2 months	10.4 months
CORECT registry	Erbitux - 2. line	17.9 months	6.1 months
BOND[3]	Erbitux - 2. line	8.6 months	4.1 months

[1] Hurwitz H, Fehrenbacher L, Novotny W, et al. Bevacizumab plus irinotecan, fluorouracil, and leucovorin for metastatic colorectal cancer. New England Journal of Medicine 2004; 350 (23): 2335-2342. [2] Saltz LB, Clarke S, Diaz-Rubio E, et al. Bevacizumab in combination with oxaliplatin-based chemotherapy as first-line therapy in metastatic colorectal cancer: A randomized phase III study. Journal of Clinical Oncology 2008; 26 (12): 2013-2019. [3] Cunningham D, Humblet Y, Siena S, et al. New England Journal of Medicine 2004; 351 (4): 337-345

Predictions of therapeutic burden: a base for equity monitoring

Input:
epidemiological estimates



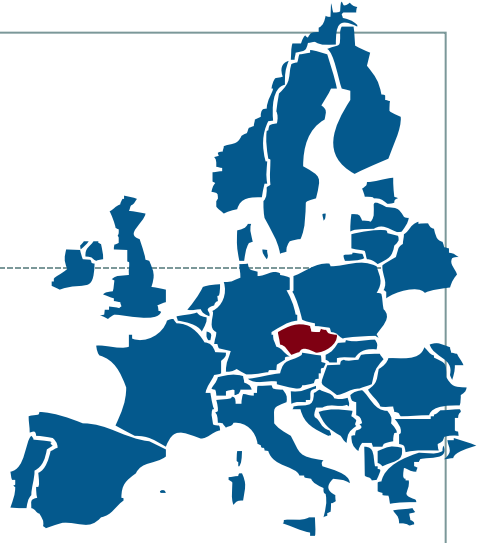
Outcome: predicted therapeutic load

Number of patients initiating treatment: comparison of reality in CORECT registry and predictions

Regions	Year 2010		Year 2011		Year 2012	
	No. of patients initiating treatment: CORECT registry[A]	Prediction[B]	No. of patients initiating treatment: CORECT registry[A]	Prediction[B]	No. of patients initiating treatment: CORECT registry[A]	Prediction[B]
xxx	158 (28%)	567 (511; 623)	132 (20%)	652 (593; 711)	179 (26%)	700 (656; 744)
xxx	62 (35%)	177 (155; 199)	42 (23%)	179 (157; 201)	59 (31%)	193 (170; 216)
xxx	54 (19%)	282 (243; 321)	67 (23%)	289 (251; 327)	65 (21%)	315 (286; 344)
xxx	47 (20%)	233 (208; 258)	53 (25%)	216 (192; 240)	43 (18%)	235 (210; 260)
xxx	56 (48%)	117 (99; 135)	51 (46%)	112 (95; 129)	57 (46%)	124 (106; 142)
xxx	127 (92%)	138 (119; 157)	91 (64%)	143 (123; 163)	83 (52%)	159 (138; 180)
xxx	70 (52%)	134 (115; 153)	47 (36%)	129 (110; 148)	54 (39%)	140 (121; 159)
xxx	38 (26%)	146 (126; 166)	28 (20%)	141 (121; 161)	31 (21%)	151 (131; 171)
xxx	198 (69%)	285 (257; 313)	229 (76%)	300 (272; 328)	178 (54%)	329 (299; 359)
xxx	59 (33%)	179 (157; 201)	52 (30%)	173 (151; 195)	37 (19%)	191 (168; 214)
xxx	44 (26%)	169 (148; 190)	32 (20%)	157 (136; 178)	44 (26%)	171 (149; 193)
xxx	100 (27%)	368 (336; 400)	119 (33%)	361 (330; 392)	115 (29%)	392 (359; 425)
Czech Republic	**1013 (36%)**	**2795 (2708; 2882)**	**943 (33%)**	**2852 (2764; 2940)**	**945 (30%)**	**3100 (3008; 3192)**

[A] Number of patients in registry and percentage of predicted number of patients.

[B] Estimate is accompanied with 90% confidence interval.



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Conclusions

Care for advanced CRC in the Czech Republic as highly burdened country

Conclusions

The Czech health care system is challenged by **growing number of CRC patients, primarily diagnosed in advanced stage**. Many of them are relatively young, with significant life expectancy.

Treatment of advanced CRC is standardized and includes several very cost demanded modalities. **Without significantly strengthened early CRC detection, the economic demands will inevitably grow**.

Even nowadays, the running information system indicates **significant non-equity in access of advanced CRC patients to target therapy**.

What can we expect if the incidence further grows?

Functional clinical registries prove that **therapy of advanced CRC can offer substantial benefits** for the patients, both in safety and efficacy – including overall survival.