

CML Management in Emerging Countries

Access to treatment (Eastern Europe)

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What are the main goals of CML treatment worldwide?

2000

- escape from BC
- survival
- CHR, CCgR

2006

- escape from BC
- survival
- CHR, CCgR
- MMR
- QoL

2013

- escape from BC
- survival
- CHR, CCgR
- MR3/>MR4
- QoL
- fast response

2017

- escape from BC
- survival
- CHR, CCgR
- MR3/>MR4.5
- QoL
- fast response
- TFR

How we can achieve those goals?

- imatinib
- basic monitoring
- dose finding
- better BMT

- imatinib
- mol monitoring
- ELN recom.
- AE solving
- dose escalation

- imatinib
- dasatinib 1&2nd
- nilotinib 1&2nd
- molecular stand.
- ELN 2013

- imatinib
- dasatinib 1&2nd
- nilotinib 1&2nd
- bosutinib
- ponatinib
- molecular stand.
- ELN 2017
- BMT (alo, haplo..)

Several starting questions?

1. How many of you have regular access to imatinib?
2. How many of you have access to molecular monitoring?
3. How many of you have access to any second line TKI?
4. What are goals of CML treatment in your country?
 - A. only escape from blast phase – survival (hematol. response)
 - B. achieve good clinical effect – survival (cytogenetic response)
 - C. achieve optimal effects – molecular response MR3 or better
 - D. consider treatment free remission as treatment goal?

Main European goals in CML treatment are same!

Leader in defining those goals is European LeukemiaNet



Standardization of BCR-ABL quantification in Europe – 2013

64 participating laboratories in 28 countries




ELN LeukemiaNet[®]
European

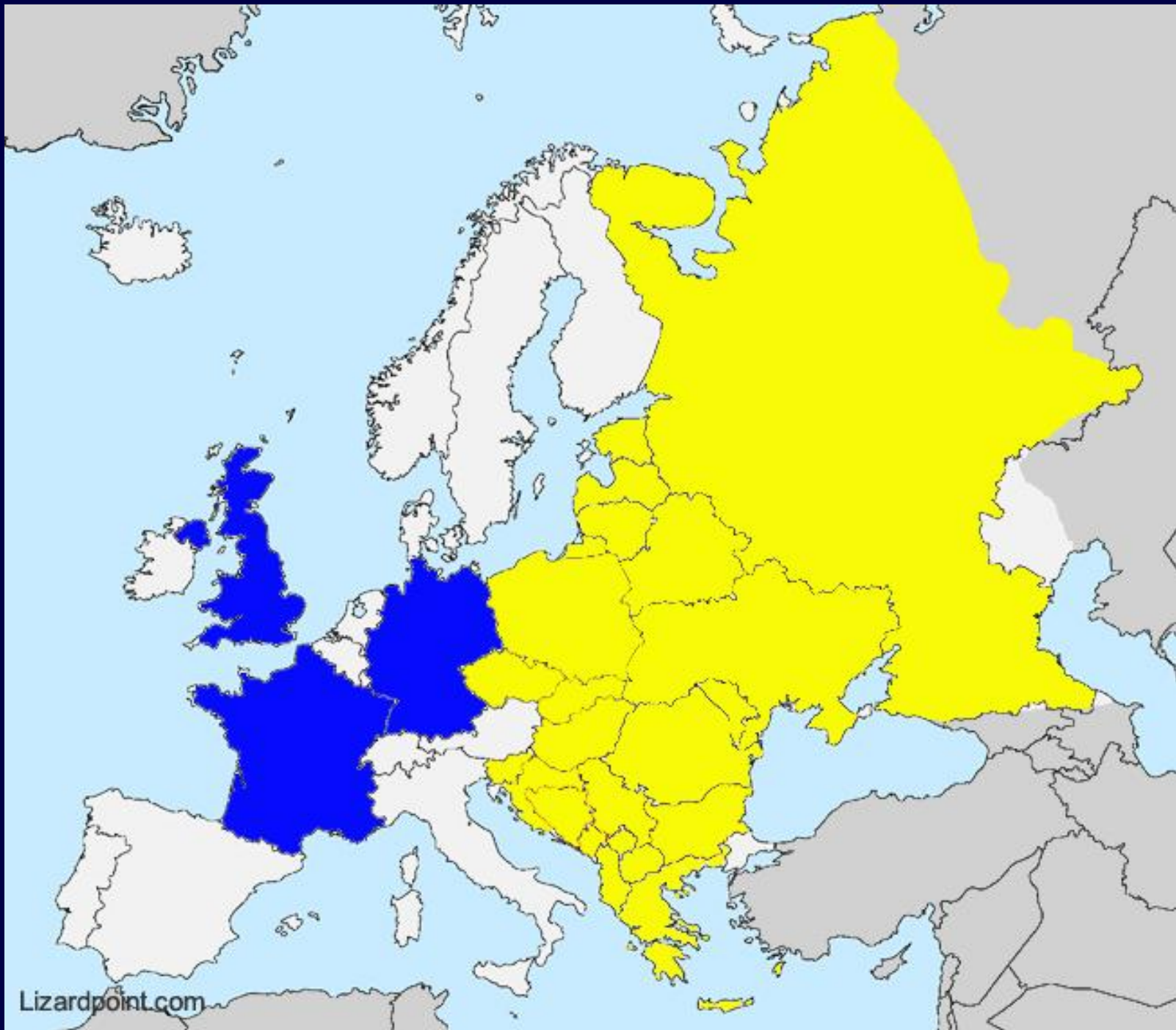
EUTOS for CML



European Treatment and Outcome Study



-  Countries with a ref lab with validated CF
-  Countries using a ref lab in a different country
-  Countries with a ref lab – validation pending



Who are we? (inhabitants)



	Estonia	1.318.705
	Latvia	1.953.200
	Lithuania	2.810.865
	Poland	38.422.346
	Czech	10.610.947
	Slovakia	5.435.343
	Hungary	9.797.561
	Slovenia	2.065.895
	Croatia	4.154.200
	B&H	3.531.159
	Serbia	7.058.322
	Montenegro	642.550
	Albania	2.876.591
	KiM	2.100.000
	Macedonia	2.103.721
	Russia	144.526.636
	Belarus	9.504.700
	Ukraine	42.418.235
	Moldova	2.998.235
	Romania	19.638.000
	Bulgaria	7.101.859
	Greece	10.816.286

Total 342.653.833

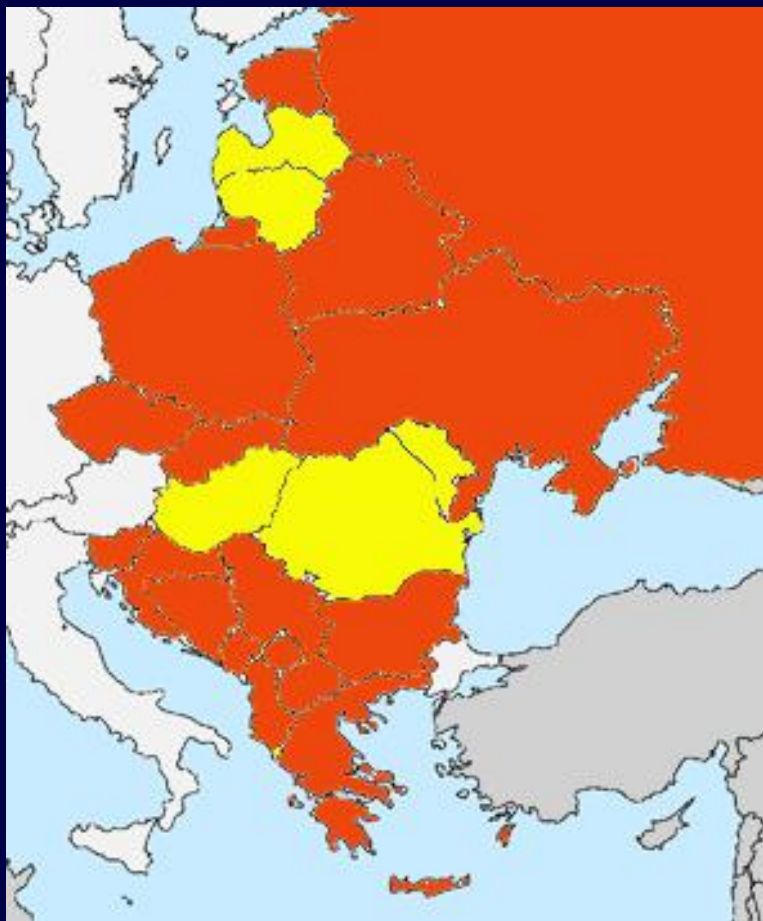
~ USA

Without
Russia 198.127.197

~ UK+FRA+GER

This figures will
be used in further
presentation

Who provided data



I would like to thank to
all my colleagues,
patient groups,
pharma representatives..

for their help in gathering
all data for this
presentation

Population data, Gross Domestic Product (GDP) and health expenditures /expressed as purchasing power parity (PPP), so called international \$/, were taken from Wiki, World Bank and other public sources
All other values are given in € per month, provided by various sources

Analysis



Poland

38422346

inhabitants



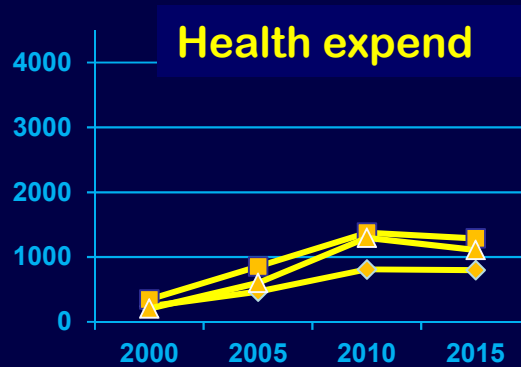
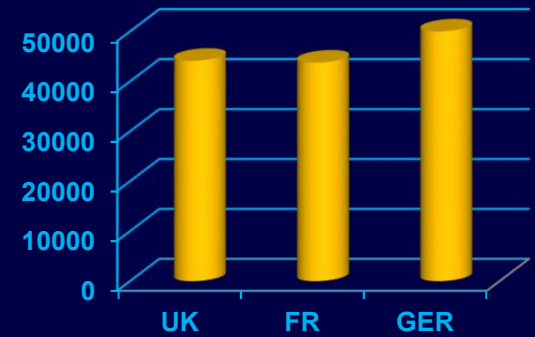
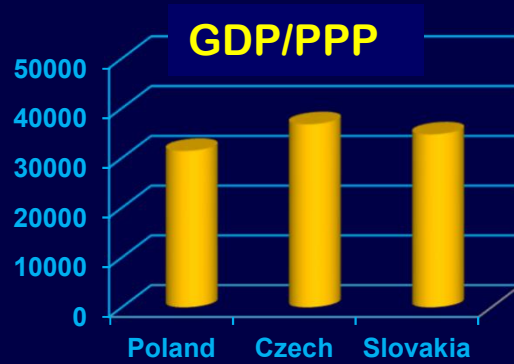
Czech

10610947

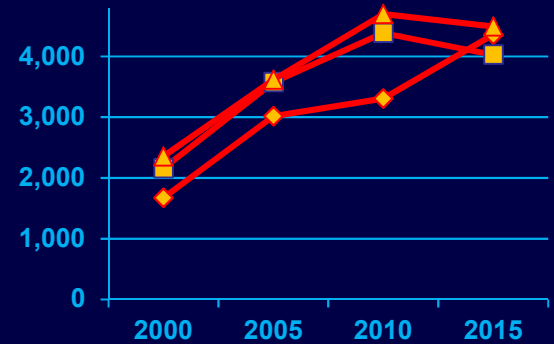


Slovakia

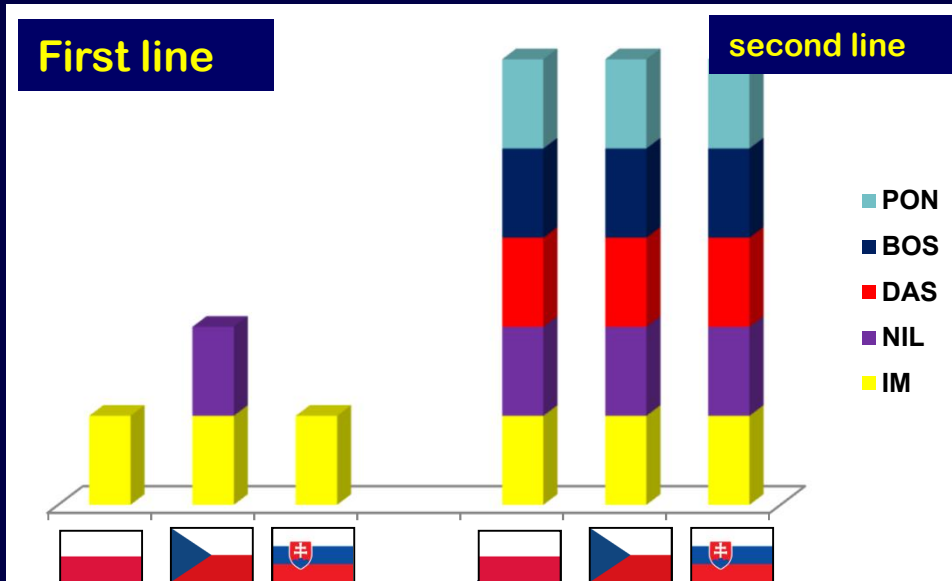
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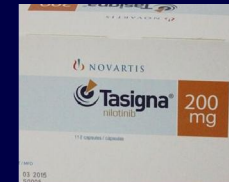
◆ Poland
■ Czech
▲ Slovakia



Analysis



IM generic (700-950€)



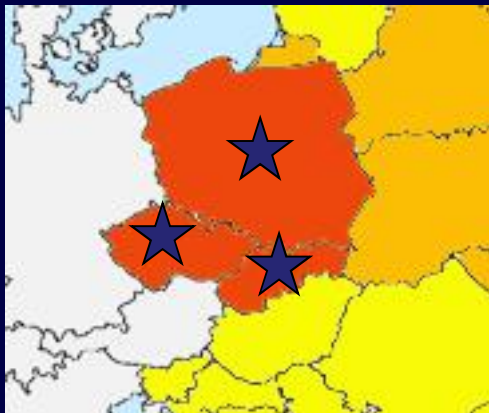
branded (3000-3800€)

only T315I*

branded (6200-10800€)



Monitoring



Poland 20 labs,
TaqMan MR4.5, GeneXpert V2, MR4.5;

reimburs.
80% needs

Czech 5 labs
TaqMan & Light Cycler MR4.5,

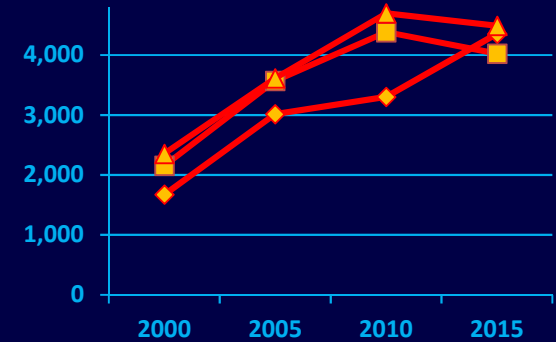
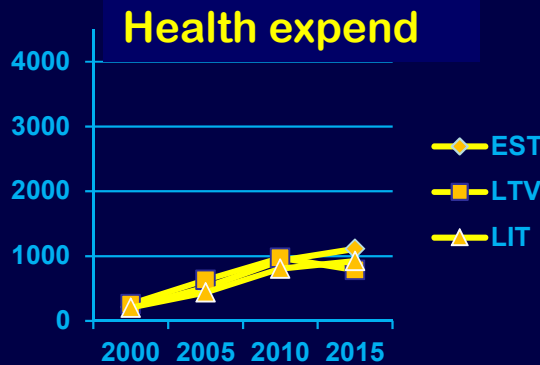
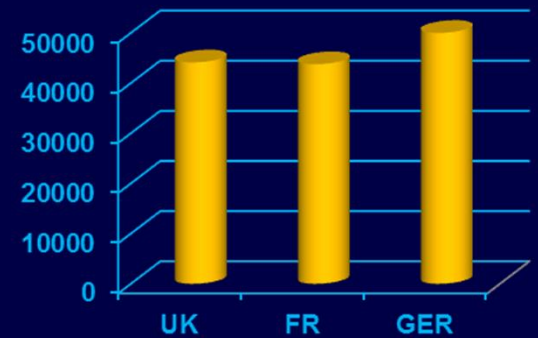
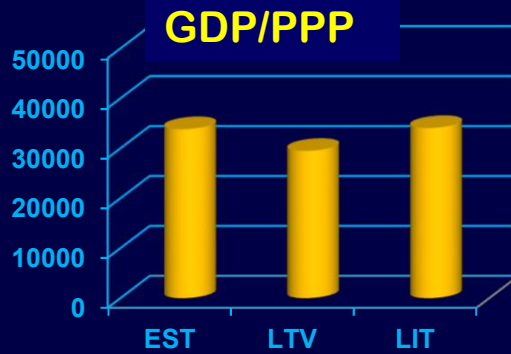
full

Slovakia
TaqMan & Light Cycler MR4.5,

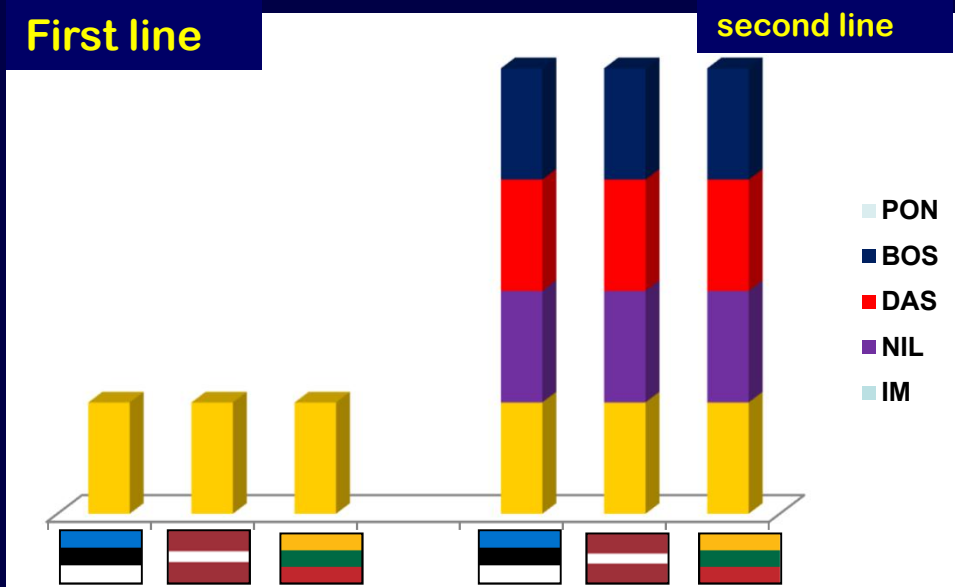
full

Analysis (2)

	Estonia	1.318.705	inhabitants
	Latvia	1.953.200	
	Lithuania	2.810.865	



Analysis (2)

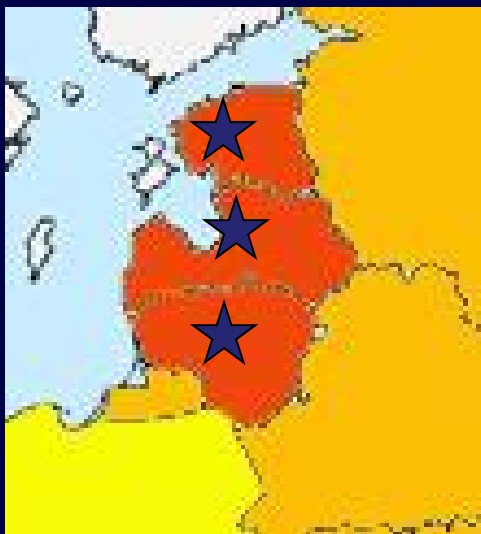


IM generic (600-800€)



branded (3500-4000€)

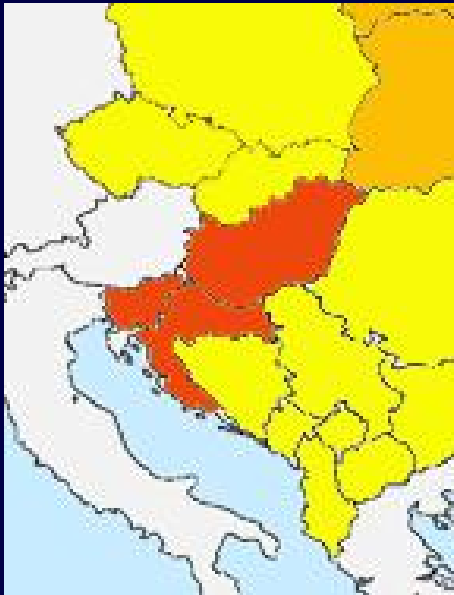
Monitoring



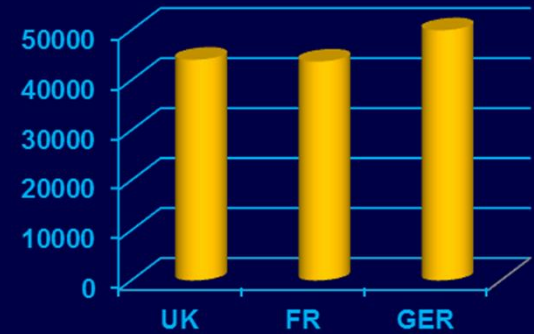
Estonia	1 lab	reimburs. full
Latvia	MR4.5	full ?
Lithuania	MR4.5	full ?

Analysis (3)

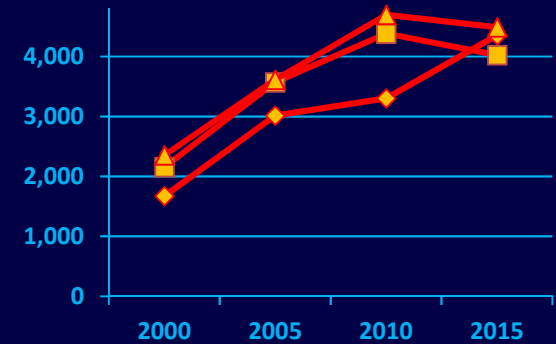
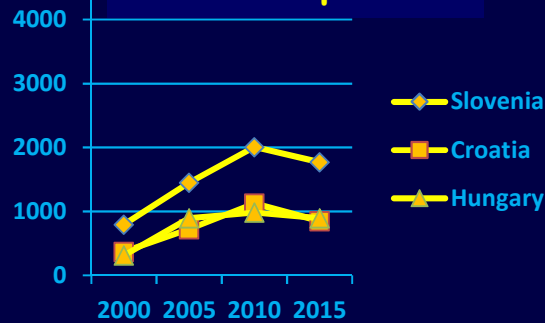
	Slovenia	2.065.895	inhabitants
	Croatia	4.154.200	
	Hungary	9.797.561	



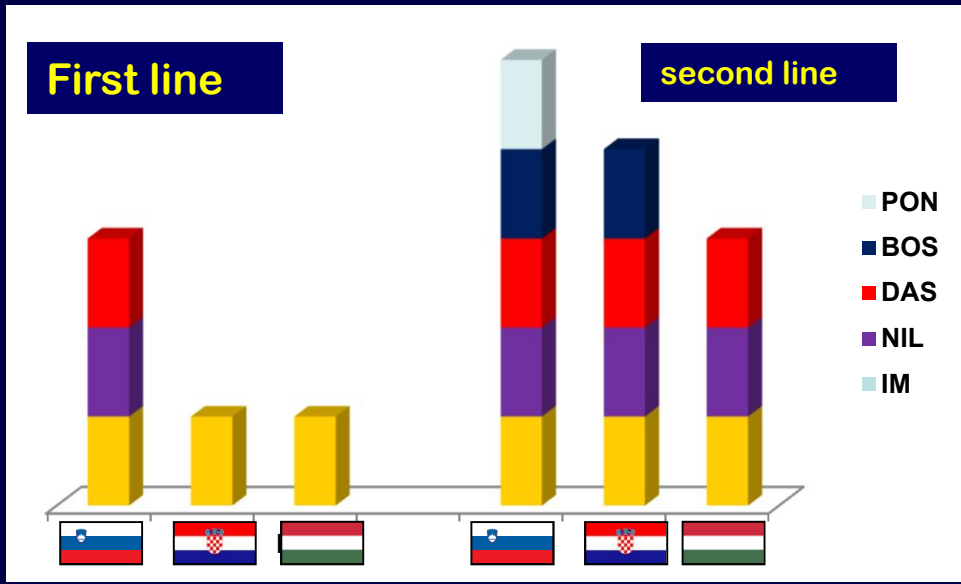
GDP/PPP



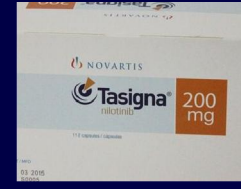
Health expend



Analysis (3)



IM generic (600-700€)



branded (3700-4000€)

only T315I*

branded (~10000€)



Monitoring



Slovenia 1 lab
TaqMan MR4.5

reimbursm.
full

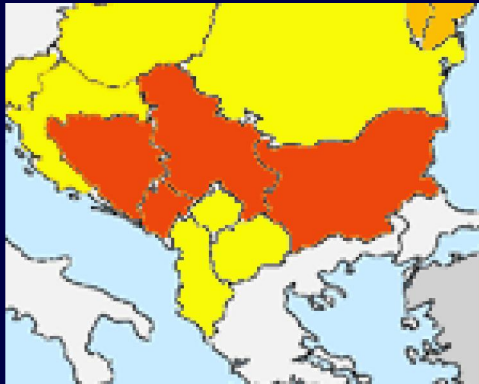
Croatia 4 labs
TaqMan & Light Cycler MR3/4.5


full

Hungary
MR4.5

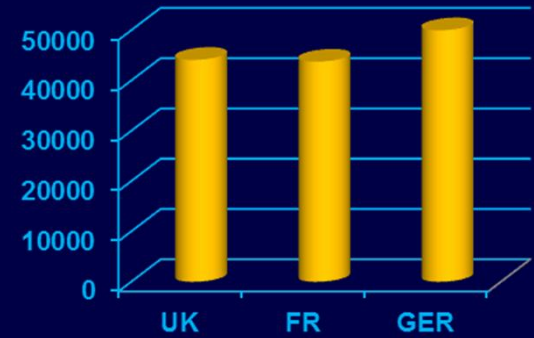
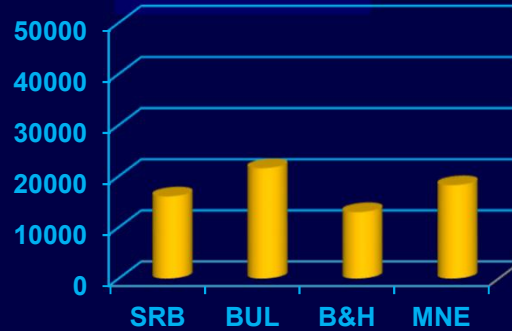
unknown

Analysis (4)

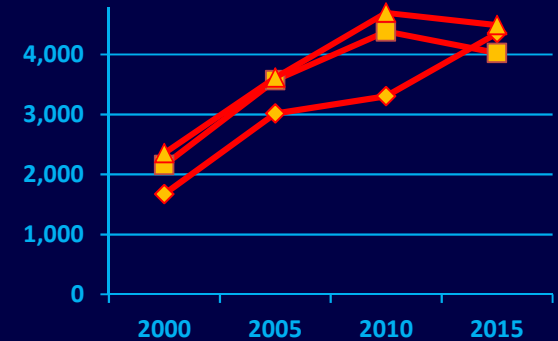
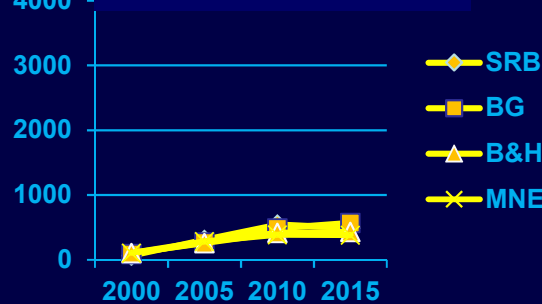


	Serbia	7.058.322	inhabitants
	Bulgaria	7.101.859	
	B&H	3.531.159	
	Montenegro	642.550	

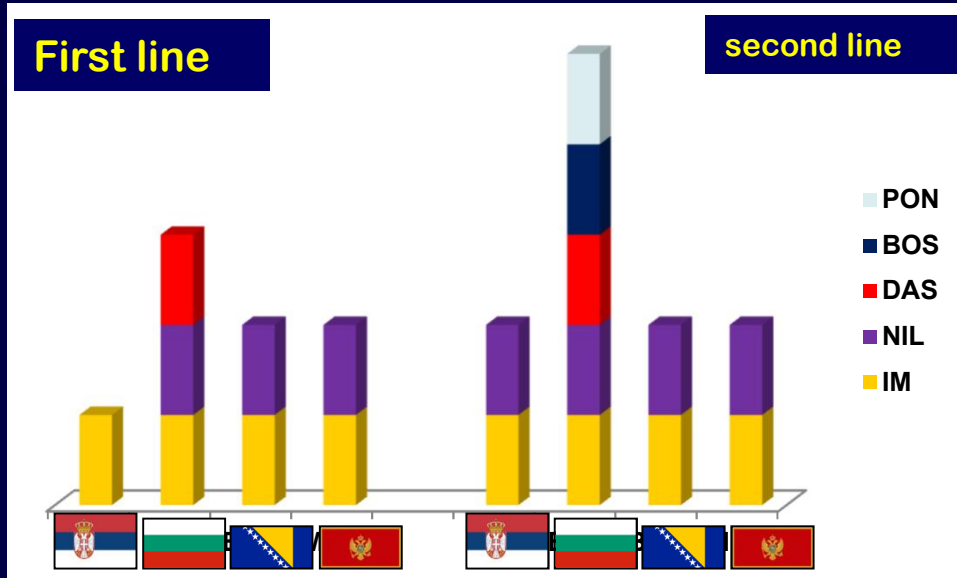
GDP/PPP



Health expend



Analysis (4)



IM generic (400-1600€)

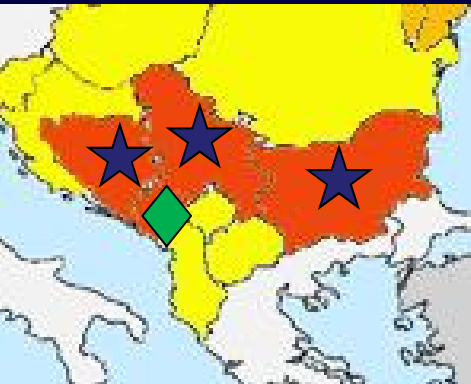


branded (2500-4000€)

**only T315I*
branded (5500€)**



Monitoring



Serbia 5 labs

TaqMan MR4.5, GeneXpert V2, MR4.5

reimburs.

½ tests, NVS

Bulgaria 3 labs

TaqMan MR4.5, GeneXpert V2 MR4.5,

partial, tests

Bosnia&Herzegovina 1 lab

Light Cycler MR4.5,

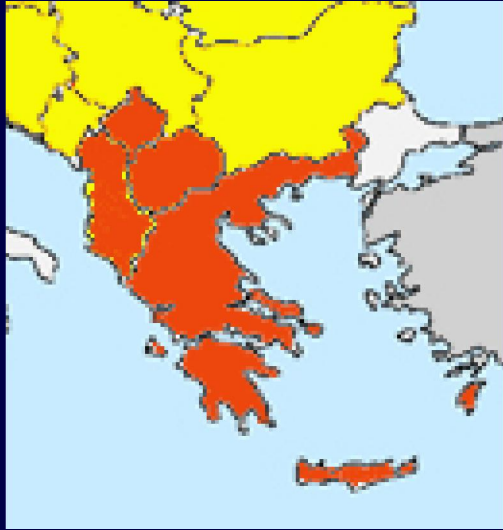
full/tests?

Montenegro 1 lab

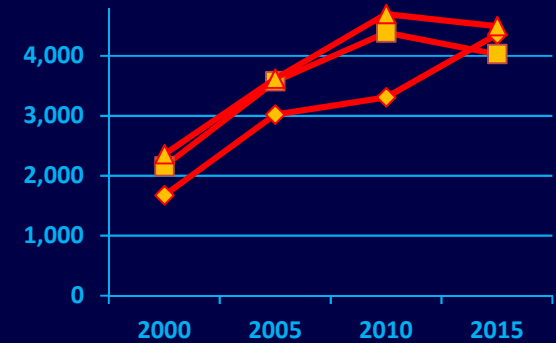
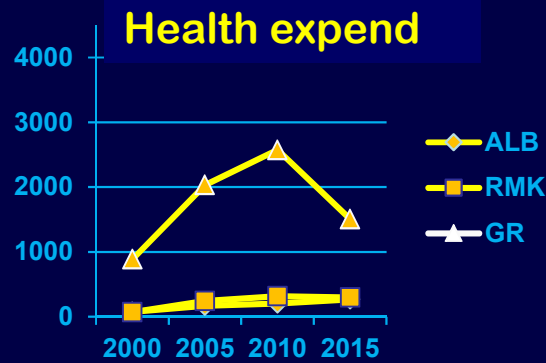
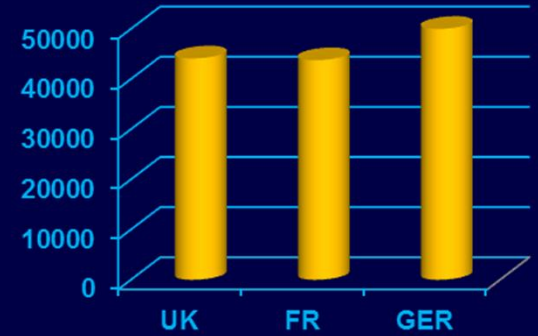
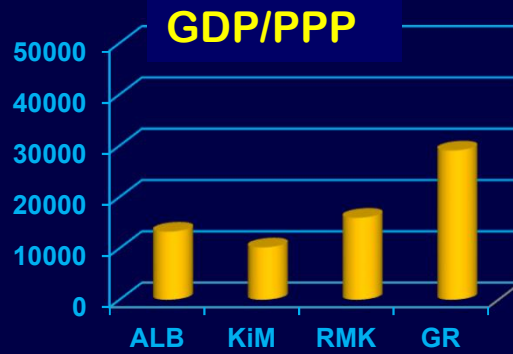
GeneXpert V1, MR3

½ tests, NVS

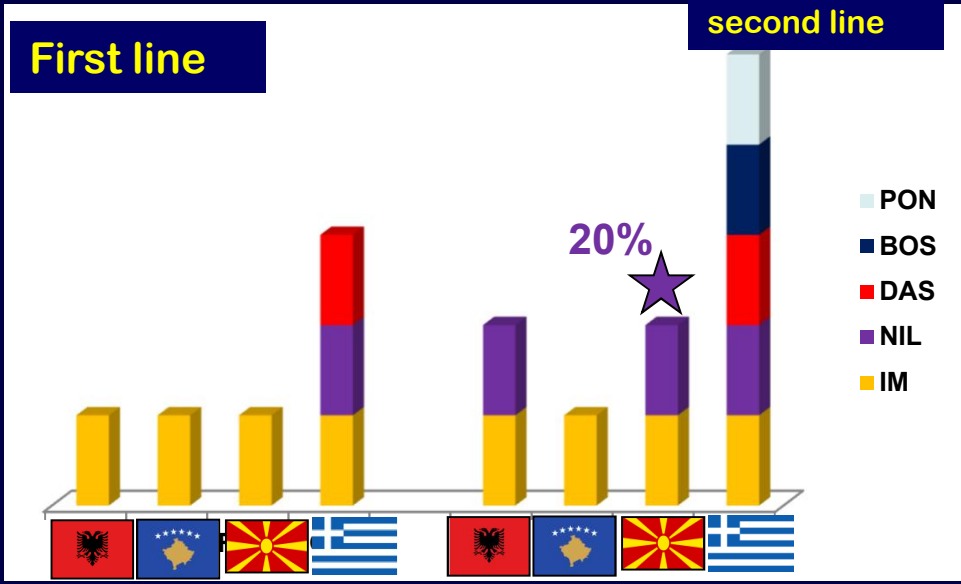
Analysis (5)



	Albania	2.876.591	inhabitants
	KiM	2.100.000	
	Macedonia	2.103.721	
	Greece	10.816.286	



Analysis (5)



IM generic (200-600€)



branded (2000-2800€)



**only T315*
branded (5100€)**

Monitoring



Albania
out of country

Kosovo
out of country

Macedonia 1 lab
LightCycler, MR3/4, GeneXpert V1

Greece, 9 labs
TaqMan, MR4.5/MR3
1500 pts monitored in MR4.5 labs

**reimbursement
pharma**



no

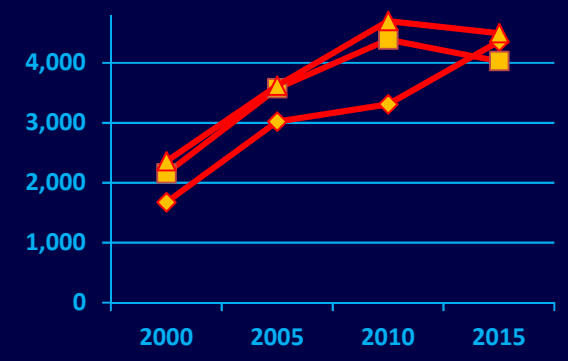
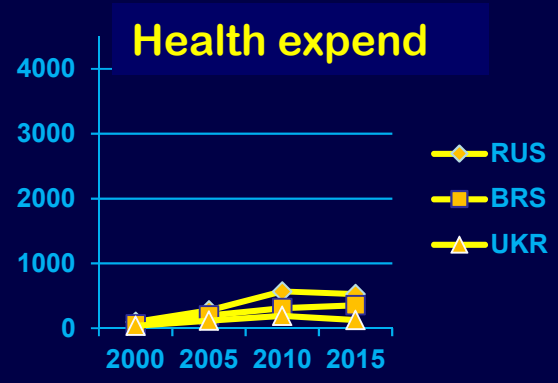
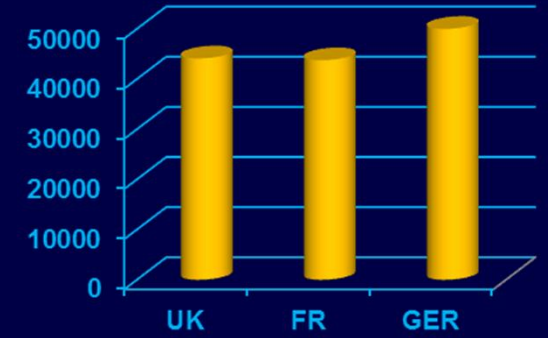
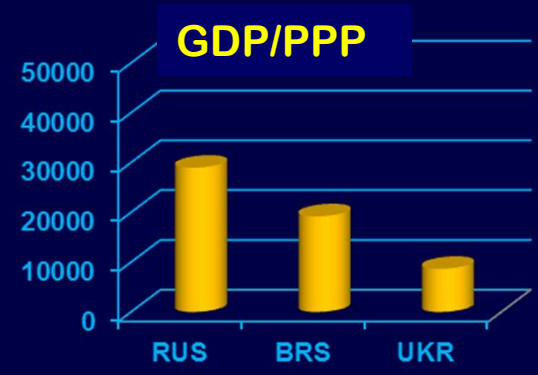
**test, 1/3 of needs
full reimbursement**

partial

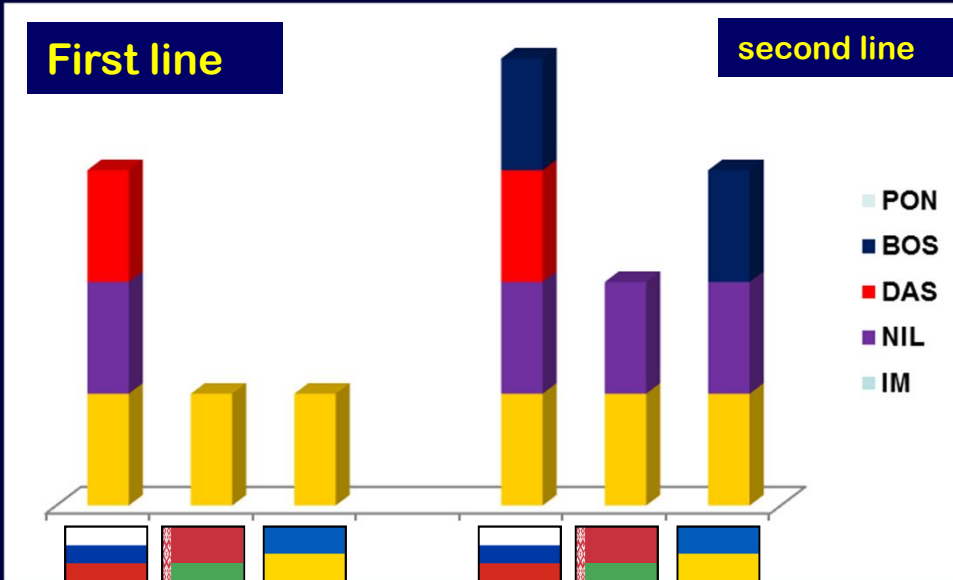
Analysis (6)



	Russia	144.526.636	inhabitants
	Belarus	9.504.700	
	Ukraine	42.418.235	



Analysis (5)

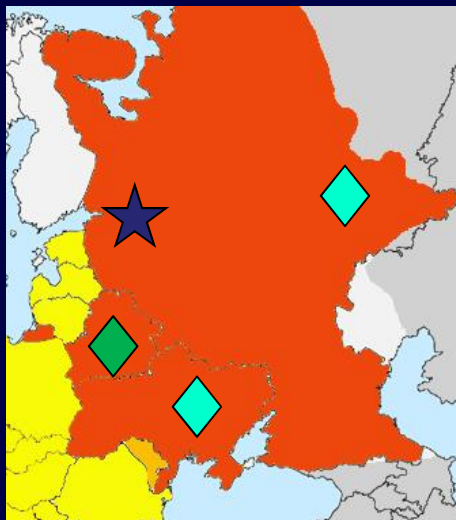


IM generic (200-500€)



branded (1700-3500€)

Monitoring



Russia 4 central labs, regional labs
TaqMan&Light Cycler MR4.5
 regional, MR4;

reimburs.
pharma
 regional

Belarus 1 lab
TaqMan MR3

full

Ukraine 1 lab
TaqMan, MR4

no

Bone marrow transplant

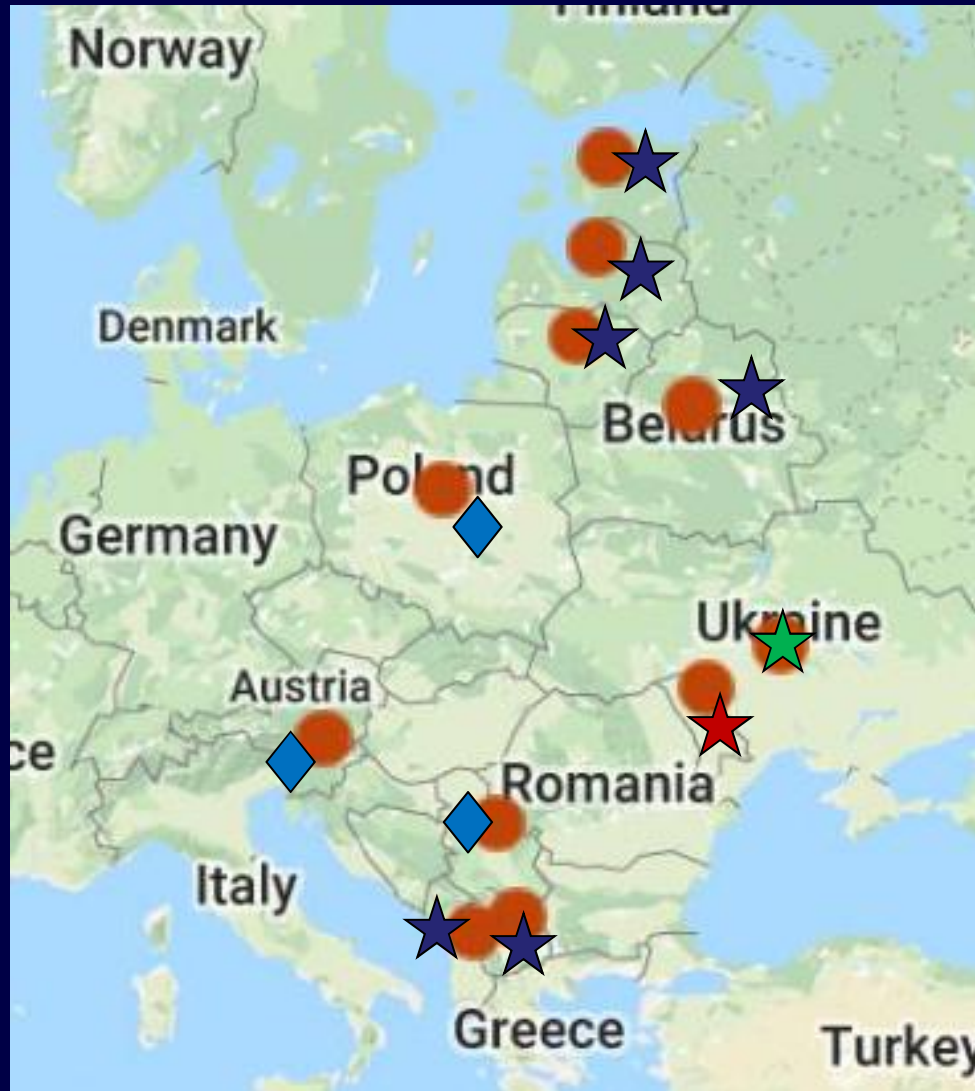
In almost all countries
allogeneic stem cell transplant
related

in most countries
as 2nd line after TKI failure
(most after 2nd TKI line treatment)
(price 50-100.000 €)

unrelated
(price 70-100.000 €)



And of course our great help The MAX Foundation projects



- ★ ponatinib
- ◆ global MAX partner (Serbia, Slovenia, Poland)
- ★ ponatinib/bosutinib
- ★ all TKI, GeneXpert



Conclusions from survey

In most of countries

- evident centralization of resources in diagnostics, monitoring and transplant
- in most countries centralized purchase of drugs; in half, centralized distribution as well
- treatment predominantly in expert centers
- drug reimbursement generally full
- PCR monitoring depends on country with variable reimbursement



What are possible treatment goals

In most of countries

- imatinib is baseline treatment, only in 7 countries (general better health funding), risk adopted 1st line treatment
- almost all countries have some second line drug(s)
- most of countries can monitor patients by cytogenetics and/or PCR with different sensitivity
- main goal in most of countries (12-14 out of 21) are MR3 with good overall survival
- in probably 7-8 out of 21 countries (1/3) TFR possibility out of clinical trial
- salvage treatment by BMT available in most countries





