

# The organization of a reliable database (Registry) of Rheumatoid Arthritis patients: the Romanian experience

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# RA Prevalence in Romania

- No local data available
- The estimated prevalence of RA is 0.5 –1%  
( around 150,000 patients)
- In 2008, 20,000 patients were hospitalized for RA in Romania

# Treatment in RA

## First line therapy

Methotrexate  
7,5-20mg/wk

Leflunomide  
20mg/day

Sulfasalazine  
2-3g/day

HCQ  
400mg/day

Gold Salts, Ciclosporine 3-5mg/kg/day  
Azathioprine 100mg/day

## Second line therapy

- Active RA (DAS28>5,1), ESR>28mm/h, CRP>20mg/l, morning stiffness >1h, despite
  - previous treatment with minimum 2 DMARDs, for at least 12 wks each

## TNF blockers:

Infliximab, Etanercept, Adalimumab

**Non-responders switch to one or more TNF alfa blockers  
or to Rituximab**

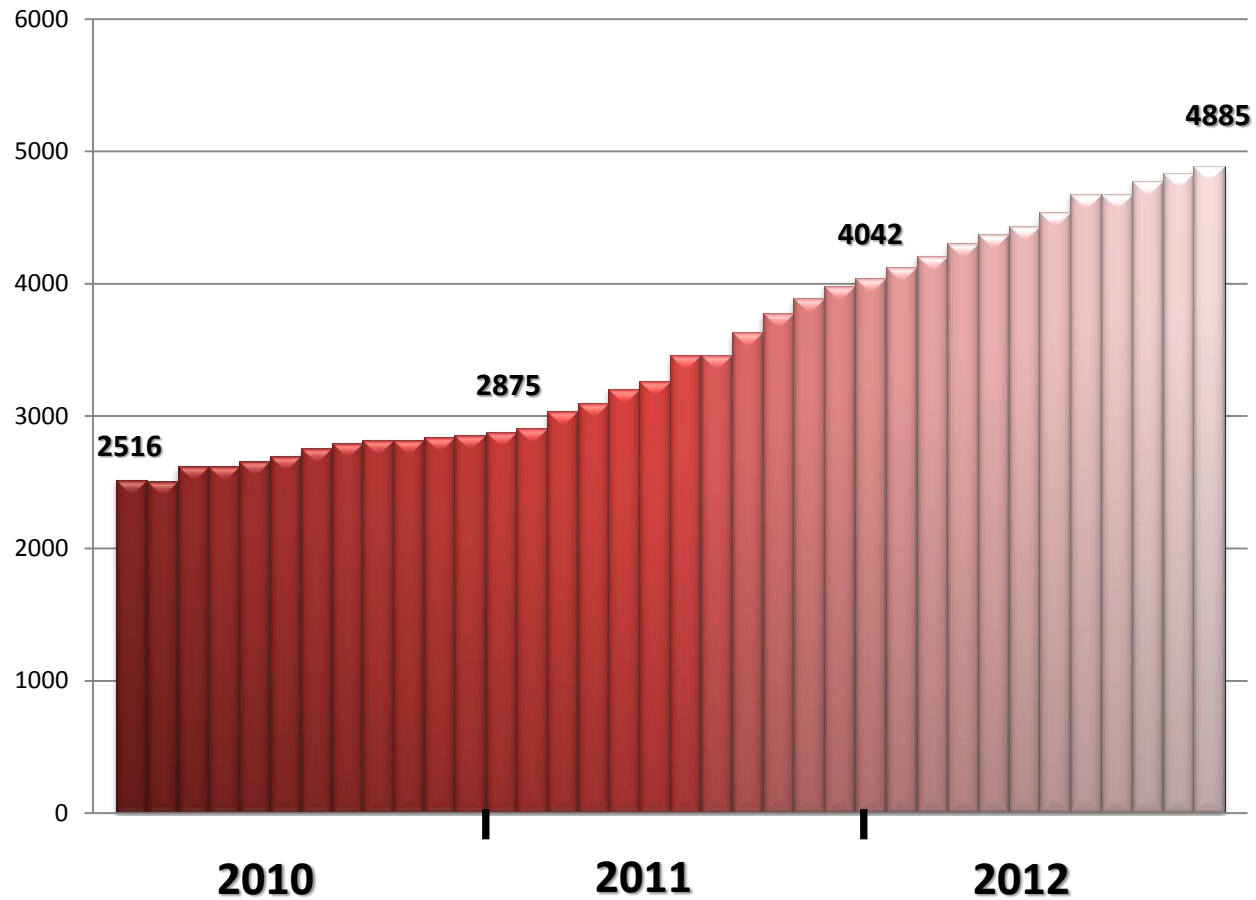
Certolizumab , Golimumab Tocilizumab, Abatacept  
Are available but not reimbursed

# Total Number of Patients treated with Biologics in Romania (2012) \*

<b>RA</b>	<b>4885</b>
<b>AS</b>	<b>1859</b>
<b>PsA</b>	<b>913</b>
<b>JIA</b>	<b>127</b>
<b>TOTAL</b>	<b>7108</b>

\* Data from National Health Insurance House

# Total number of RA patients treated with Biologics in Romania



\* Data from National Health Insurance House

# Romanian Registry of RA Patients

- The aim is to obtain data for all RA patients on biologic therapy, related to:
  - Patient demographics
  - Disease diagnosis
  - Disease course & activity (DAS28)
  - Imaging (optional): US, Rx, MRI
  - Disease therapy, including non-biologic DMARD's
  - Treatment efficacy (long-term)
  - Treatment safety (long-term)
  - Treatment failures
  - Cost-effectiveness:
    - Direct costs (hospitalization, medication, visits to rheumatologist)
    - Indirect costs (welfare, loss of productivity, absenteeism)

# Romanian Registry of RA Patients: timeline

- December 2011: Funding agreement for registry with pharma companies that have registered biologic therapies for RA
- January 2012: The software provider was selected
- October 2012: A demo version of the registry is available
- February 2013: Registry is fully active, all patients with biologics prescriptions have to be registered

# Data security



Utilizator:

Parola:

Cod parafa:

[Mi-am uitat parola](#)

[Autentificare](#)

Accesul in aplicatie este permis numai utilizatorilor autorizati RNPPR



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5 Comorbidities

6 Medication

7 Pulmonary and hepatic status

8 Markers of activity for PR

81 DAS Score

82 EURO QoL EQ-5D

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## Patient data

Form entered retroactively? ☐

The specialist that confirmed the initiating criteria:  Speciality of attending physician 

Form filled in by 

Last name 

First name 

CNP 

Born  Age 

Sex ☐ M ☒ F

Reproductive status ☐ No ☐ Yes

Phone number 

Address 

Height(cm) 

Weight(kg) 

Smoker ☐ No ☐ Yes

Retired ☐ No ☐ Yes

Level of education 

Living environment 

Professional activity status ☐ No ☐ Yes

Insured ☐ No ☐ Yes

Informed consent obtained? ☐ No ☐ Yes

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## Disease data

Symptoms onset

month  year 

Diagnosis date

month  year 

Joint disorder

- ☐ 1 large joint
- ☐ 2-10 large joints
- ☐ 1-3 small joints
- ☐ 4-10 small joints
- ☐ >10 joints, 1 small joint

Serology

- ☒ FR ☐ <3XN ☐ >3XN
- ☒ ac a CCP ☐ <3XN ☐ >3XN

Inflammation

- ☐ ESR>28mm/h
- ☐ CRP>3XN

Duration

- ☐ More than 6 weeks
- ☐ Less than 6 weeks

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### Systemic disorder

☐ Rheumatoid nodules

☐ Sicca syndrome

☐ Vasculitis

☐ Felty syndrome


☐ Raynaud syndrome

☐ Lymphadenopathy

☐ Pulmonary fibrosis

☐ Ocular damage

☒ **Serositis**


 Date:  

Comments:

☐ Pleuritis

☐ Pericarditis

☒ **Renal damage**

 Date:  

Comments:

☐ proteinuria < 1g/24h

☐ proteinuria 1-3,5 g/24h

☐ proteinuria > 3.5g/24h

☐ microscopic hematuria

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## Joint surgery and prosthesis

Interventions

- ☐ Arthroscopy  
☐ Sinovectomy  
☐ Prosthesis

Description:

Joint:

☒ Uni ☐ Bilateral

Date of intervention

☒ Other interventions

Type of interventions

Date of intervention:

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### Comorbidities

- ☐ Acute infections
- ☐ Chronic infections
- ☐ TB
- ☐ Hypertension
- ☐ CAD
- ☐ Heart Failure
- ☐ Diabetes mellitus
- ☐ Dyslipidemia
- ☐ Peripheral vascular disease
- ☐ Stroke
- ☐ Parkinson disease
- ☐ Demyelinating disorders
- ☐ Epilepsy
- ☐ Asthma
- ☐ Gastrointestinal disorders - GDU
- ☐ Hepatic disorders
- ☐ Inflammatory bowel disease
- ☐ Psoriasis
- ☐ Renal disorders
- ☐ Neoplasia
- ☐ Hematologic disorders
- ☐ Osteoporosis
- ☐ Arthritis
- ☐ Fibromyalgia
- ☐ Psychiatric disorders
- ☐ Known hypersensitivities
- ☐ Thyroid impairment
- ☐ Alcoholism
- ☐ Other significant

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## Medication

### History of non-biological treatment

Dmard	Date of the first dose	Date of the last dose	Current treatment	Dosage	Inefficiency	Intolerance	Adverse events	Other
Metotrexat								
Leflunomide								
Sulfasalazina								
HCQ								
Ciclosporina								
Azatioprina								
Ciclofosfamida								
Gold salts								

### CORTICOIDS (prednisone or prednisone equivalent in mg/day)

- ☒ <10 mg/day  
☐ >10 mg/day  
☐ > 3 monts within the last year

### Concomitant medication

Brand name	DCI	Date of initiation	Dosage mg	Frequency	

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### Pulmonary and hepatic status

☐ X-ray

 Quantiferon ☐ Negative ☐ Positive

 Ac HCV ☐ Negative ☐ Positive

 Ag HBs ☐ Negative ☐ Positive

Pneumologist opinion

Other viral markers

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### Markers of activity for PR

HAQ Score What time you woke up today? What time the maximum improvement in stiffness occurs? Duration of morning stiffness (minutes) 

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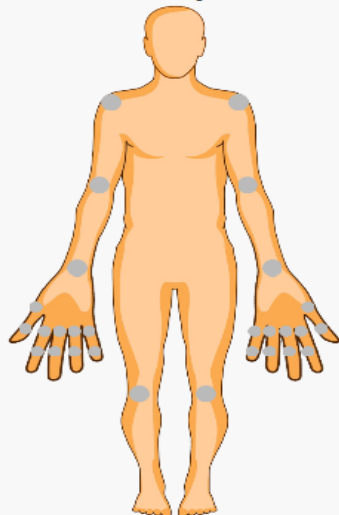
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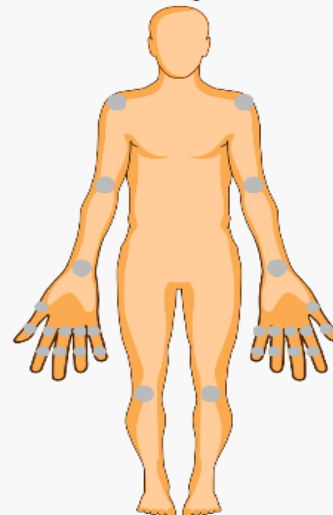
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### DAS Score

Swollen joints



Tender joints


Mark the swollen/  
tender joints


Swollen joints

☐ ESR:  mm/h

Tender joints

☐ CRP:  mg/dl

Joints that cannot be evaluated

Name of the person who performed the joints count: 

#### Visual analogue scale

General health status (rated by patient) 

General health status (rated by doctor) 


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### Health outcome questionnaire - EQ-5D



#### Mobility

- ☐ I have no problems in walking about
- ☐ I have some problems in walking about
- ☐ I am confined to bed

#### Self-care

- ☐ I have no problem with self-care
- ☐ I have some problems washing or dressing myself
- ☐ I am unable to wash or dress myself

#### Usual Activities (e.g. work, study, housework, family or leisure activities)

- ☐ I have no problems with performing my usual activities
- ☐ I have some problems with performing my usual activities
- ☐ I am unable to perform my usual activities

#### Pain/Discomfort

- ☐ I have no pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have extrem pain or discomfort

#### Anxiety/Depression

- ☐ I am not anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am extremely anxious or depressed

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## Biological evaluation

Biological evaluation	Date	Result	Normal values
Rheumatoid Factor(UI/mL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Anti CCP Ab (UI/mL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Antinuclear Ab (UI/mL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
ESR(mm/h)	<input type="text"/>	<input type="text"/>	<input type="text"/>
C Reactive Protein (mg/dl)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Hb (g/dL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Leucocytes (x1000/uL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Trombocytes (x1000/uL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
ASAT (UI/L)	<input type="text"/>	<input type="text"/>	<input type="text"/>
ALAT (UI/L)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Glycemia(mg/dL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Creatinine(mg/dL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Alkaline Phosphates (UI/l)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cholesterol(mg/dL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Triglycerides(mg/dL)	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other significant investigation	<input type="text"/>	<input type="text"/>	<input type="text"/>

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## ADVERSE EVENTS

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### General data

Date of event onset	<input type="text"/>		
Event	<input type="radio"/> expected (according to SPC) <input type="radio"/> unexpected	Data of event cessation	<input type="text"/>
		Duration	<input type="text"/> hours <input type="text"/> days
Frequency	<input type="radio"/> single <input type="radio"/> intermittent <input type="radio"/> persistent <input type="radio"/> recurrent		
Relation with the biological therapy	<input type="radio"/> no relation <input type="radio"/> possible <input type="radio"/> probable <input type="radio"/> certain		

### Description

- ☐ Pancytopenia
- ☐ Infection
- ☐ Tuberculosis
- ☐ Solid malignancies
- ☐ Malignant lymphoproliferations
- ☐ Demyelinisant disorders
- ☒ **Congestive HF**
  - ☐ Newly diagnosed ☐ Aggravated
  - Ultrasound evaluation ☐ No ☐ Yes
  - Comments
- ☐ ACS
- ☐ Stroke
- ☐ Pregnancy
- ☐ Skin reactions
- ☐ Anafilaxy
- ☐ Immunologic abnormalities
- ☐ Other important medical events
- ☐ Reactivated chronic virus B hepatitis

### Conclusions

The gravity of adverse event	<input type="radio"/> mild <input type="radio"/> moderate <input type="radio"/> severe
Important medical event	<input type="radio"/> No <input type="radio"/> Yes
Comments	<input type="text"/>
Attitude regarding biological therapy	<input type="radio"/> stop <input type="radio"/> continue <input type="radio"/> dose adjustment
Progress	<input type="radio"/> improved <input type="radio"/> cured <input type="radio"/> aggravated <input type="radio"/> fatal <input type="radio"/> unchanged
Comments:	<input type="text"/>