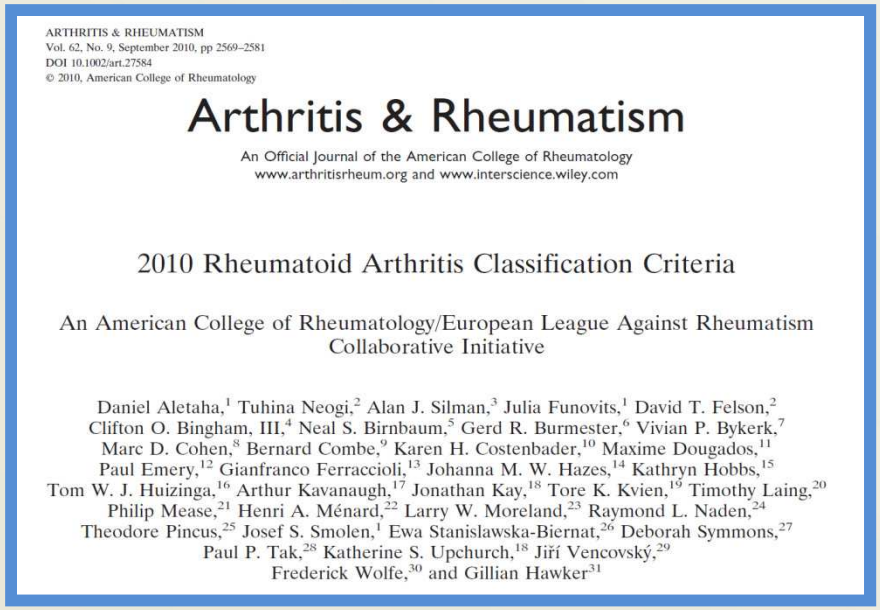
2010 ACR/EULAR Classification Criteria for Rheumatoid Arthritis

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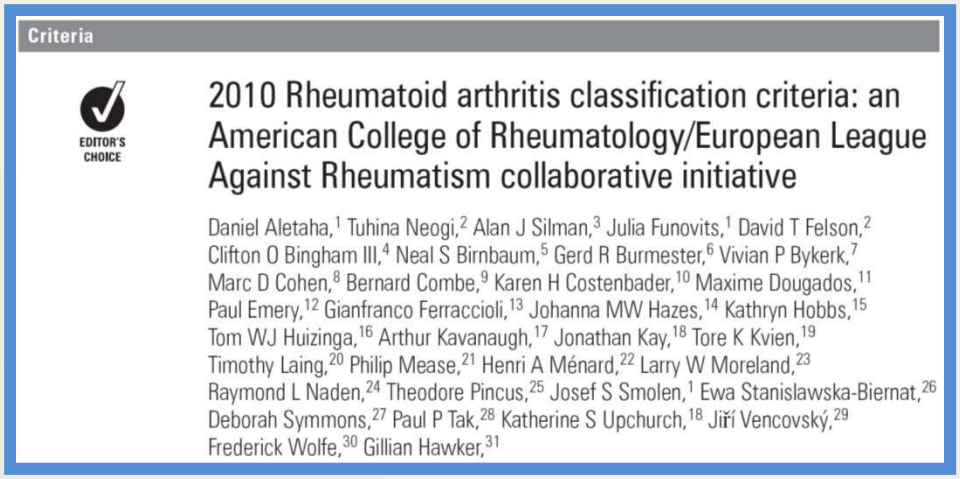
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2010 Rheumatoid Arthritis Classification Criteria

An American College of Rheumatology/European League Against Rheumatism Collaborative Initiative

Daniel Aletaha,[1] Tuhina Neogi,[2] Alan J. Silman,[3] Julia Funovits,[1] David T. Felson,[2] Clifton O. Bingham, III,[4] Neal S. Birnbaum,[5] Gerd R. Burmester,[6] Vivian P. Bykerk,[7] Marc D. Cohen,[8] Bernard Combe,[9] Karen H. Costenbader,[10] Maxime Dougados,[11] Paul Emery,[12] Gianfranco Ferraccioli,[13] Johanna M. W. Hazes,[14] Kathryn Hobbs,[15] Tom W. J. Huizinga,[16] Arthur Kavanaugh,[17] Jonathan Kay,[18] Tore K. Kvien,[19] Timothy Laing,[20] Philip Mease,[21] Henri A. Ménard,[22] Larry W. Moreland,[23] Raymond L. Naden,[24] Theodore Pincus,[25] Josef S. Smolen,[1] Ewa Stanislawska-Biernat,[26] Deborah Symmons,[27] Paul P. Tak,[28] Katherine S. Upchurch,[18] Jiří Vencovský,[29] Frederick Wolfe,[30] and Gillian Hawker[31]



Criteria

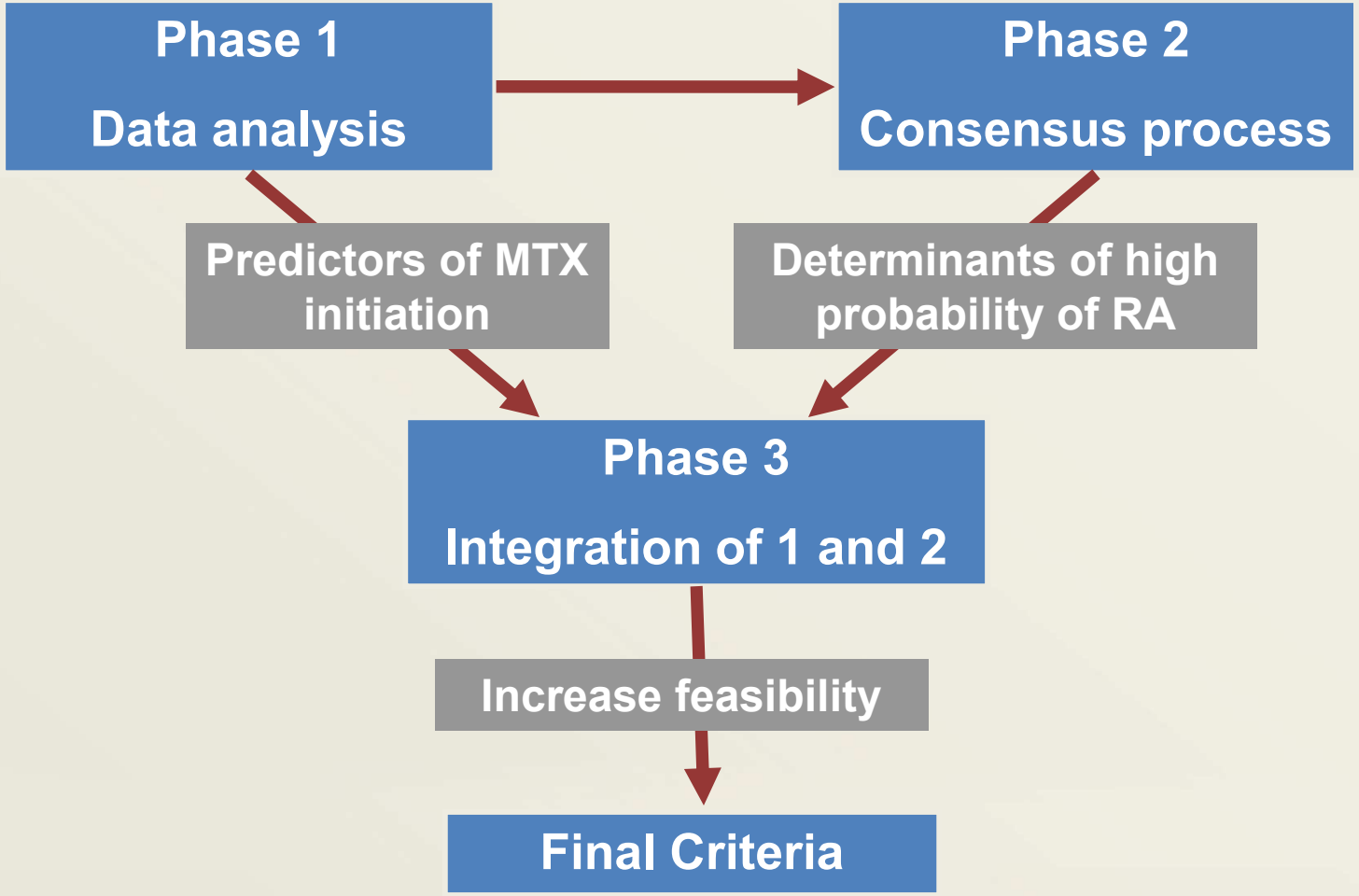
EDITOR'S CHOICE

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Phases of the Project



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Phase 1

Data Driven Approach

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Phase 1: Patients and Methods

- Patients – EARLY ARTHRITIS COHORTS
  - 3115 patients from 9 cohorts
  - Inflammatory arthritis (no other definite diagnosis) of <3 years
  - No previous DMARD/MTX treatment
- Methods – PREDICTORS OF MTX TREATMENT
  - Step 1: Univariate regression analysis of all possible variables
  - Step 2: Principal component analysis: identify themes
  - Step 3: Multivariate regression analysis with all relevant themes

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Phase 1: Three Analytic Steps



STEP 1

Univariate Regression Analysis

Identify significant variables at baseline

Gold standard: MTX treatment at one year



STEP 2

Principal Component Analysis

Identify sets of variables representing the same "theme"



STEP 3

Multivariate regression Analysis

Identify independent effects of variables and their relative contribution ("weight")

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STEPS 1 and 2: Predictors of MTX initiation

	Loadings on Factors 1-6					
Factor No (Eigenvalue)	**1** (5.33)	**2** (1.91)	**3** (1.62)	**4** (1.15)	**5** (0.99)	**6** (0.94)
Anit-Citrullinated peptide AB (0,1,2)	.104	.064	.035	.079	.094	.878
Rheumatoid factor (0,1,2)	.105	.013	.064	.053	.117	.878
CRP (0,1,2)	-.004	.101	-.049	.847	.004	.055
ESR (tertiles)	.012	.026	-.042	.847	-.042	.121
HAQ (tertiles)	.103	.180	.343	.555	.062	-.074
SJC (1,2-6,7-28)	.612	.356	.198	.075	.526	.125
MCP swelling (yes/no)	.839	.103	.282	.017	.149	.158
PIP swelling (yes/no)	.287	.138	.082	-.003	.852	.176
Wrist swelling (yes/no)	.165	.865	.140	.119	.055	.102
MTP swelling (yes/no)	.055	.047	.024	.009	.022	.127
Tender Joint count (1, 2-6, 7-28)	.268	.204	.767	.058	.384	.047
MCP tenderness (yes/no)	.509	.014	.723	-.003	.108	.094
PIP tenderness (yes/no)	.103	.045	.550	-.048	.710	.098
Wrist tenderness (yes/no)	.001	.658	.599	.036	.001	.048
Symmetrical MCP swelling	.826	.205	.095	.039	.163	.062
Symmetrical wrist swelling	.229	.785	-.024	.133	.194	-.037

Loadings: **0 – 0.199** **0.2 – 0.399** **0.4 – 0.599** **0.6 – 0.799** **0.8 – 1**

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STEP 2: Relevant Themes to Predict MTX Treatment

Factor	Loading variables	Theme	Represented by
1	SJC, MCP_{SW}, $MCP_{SW\text{-}Sym}$	"MCP involvement"	MCP swelling
2	$Wrist_{SW}$, $Wrist_{TD}$, $Wrist_{SW\text{-}Sym}$	"Wrist involvement"	Wrist swelling
3	TJC, MCP_{TD}, PIP_{TD}	"Hand/finger tenderness"	PIP or MCP or wrist tenderness
4	CRP, ESR	"Acute phase response"	Abnormal CRP or abnormal ESR
5	PIP_{SW}, PIP_{TD}	"PIP involvement"	PIP swelling
6	ACPA pos., RF pos.	"Serology"	Pos. ACPA or pos. RF

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Phase 1: Results

Variable	Comparison	P	OR (95% CI)	Weight
Swollen MCP	Pres vs. abs	0.003	1.46 (1.14 to 1.88)	**1.5**
Swollen PIP	Pres vs. abs	0.001	1.51 (1.19 to 1.91)	**1.5**
Swollen wrist	Pres vs. abs	<0.001	1.61 (1.28 to 2.02)	**1.5**
Hand tenderness	Pres vs. abs	<0.001	1.80 (1.33 to 2.44)	**2**
Acute phase	Mod. vs. normal	0.172	1.24 (0.91 to 1.70)	**1**
	High vs. normal	0.001	1.68 (1.23 to 2.28)	**2**
Serology	Mod. vs. normal	<0.001	2.22 (1.81 to 3.28)	**2**
	High vs. normal	<0.001	3.85 (2.96 to 5.00)	**4**

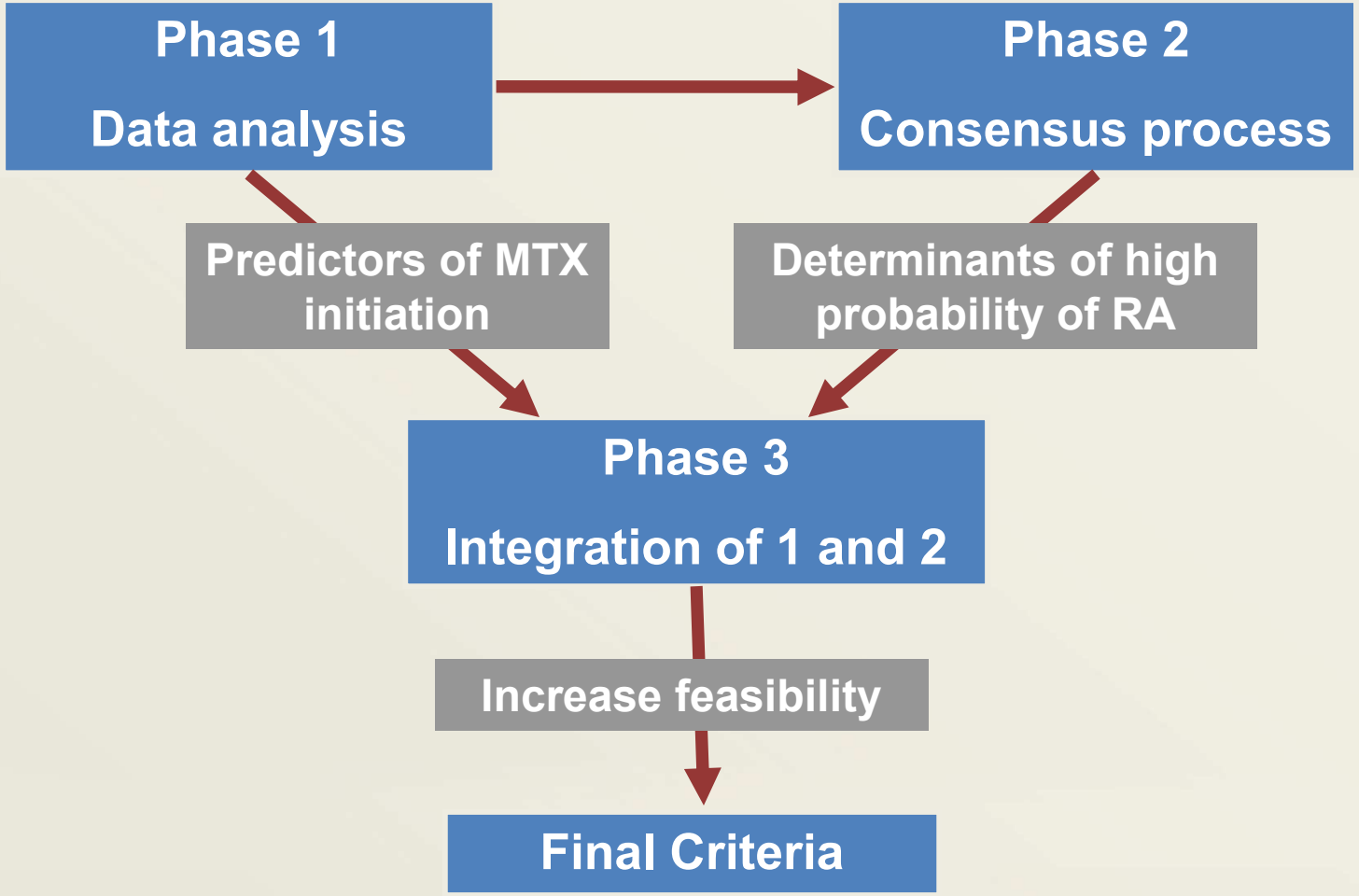
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Phase 1: Conclusion

- Swelling of small joint regions (PIP, MCP, wrist) has independent effect
- Tenderness might be also be considered as "joint involvement"
- Symmetrical involvement does not seem to have a significant incremental effect over unilateral involvement
- Abnormal acute phase response has a considerable effect
- Serology has a considerable effect, and shows a "dose-response" relationship of titres

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Phases of the Project



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Phase 2

Consensus Approach

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Phase 2: Methods

- Ranking of patient profiles by experts for their probability to develop RA
- Evidence based discussion on discrepancies in the ranking
- Specifying target population
- Developing positive and negative determinants for risk of RA (informed by Phase 1 data)
- Grouping these determinants into domains and categories
- Weighting of each category using decision analytic software

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Phase 2: Overview

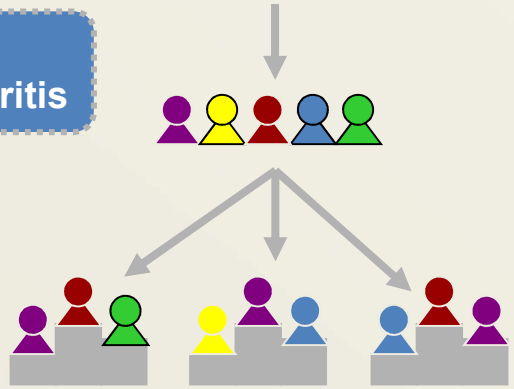
Expert panel

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Phase 2: Overview

Expert panel

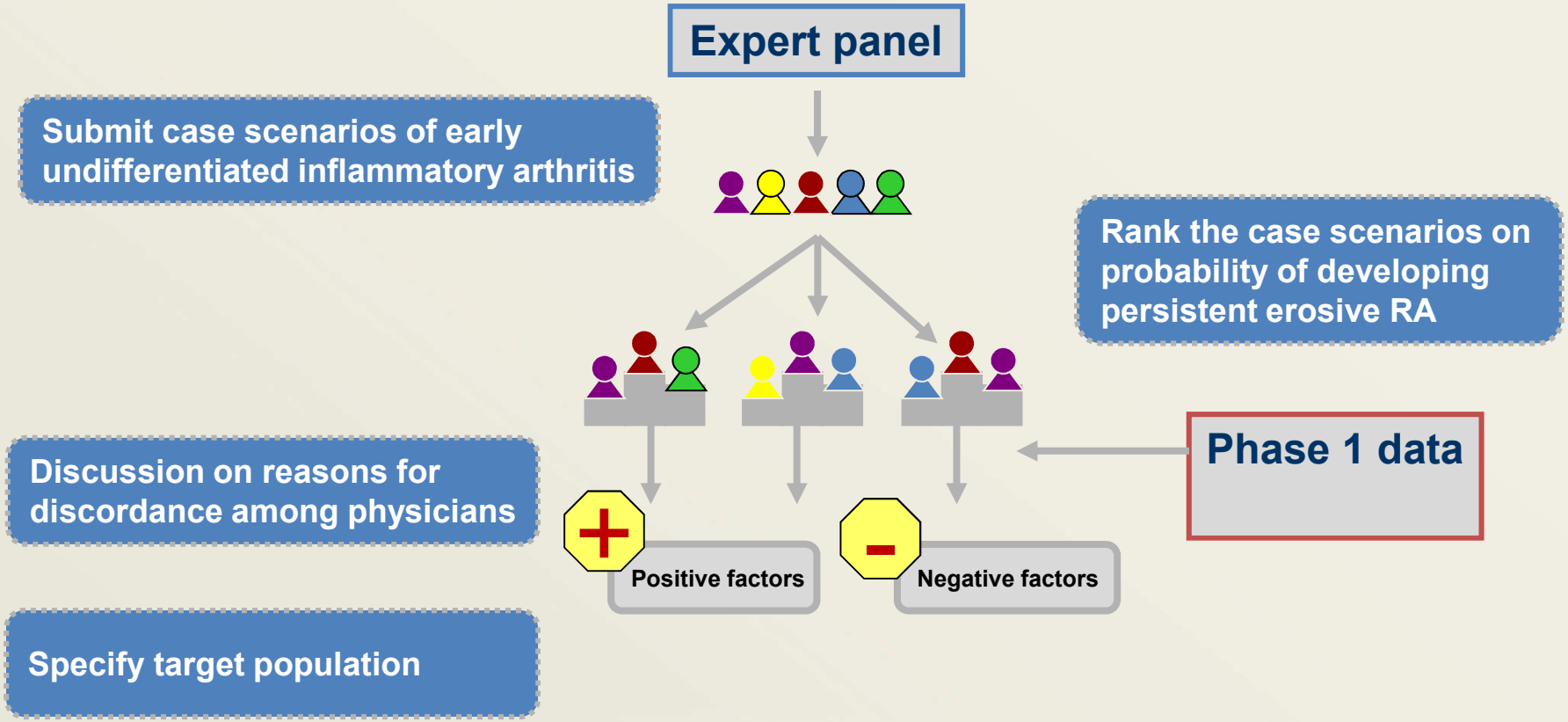
Submit case scenarios of early undifferentiated inflammatory arthritis



Rank the case scenarios on probability of developing persistent erosive RA

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Phase 2: Overview



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Phase 2: Overview

Expert panel

Submit case scenarios of early undifferentiated inflammatory arthritis

Rank the case scenarios on probability of developing persistent erosive RA

Phase 1 data

Discussion on reasons for discordance among physicians

Positive factors

Negative factors

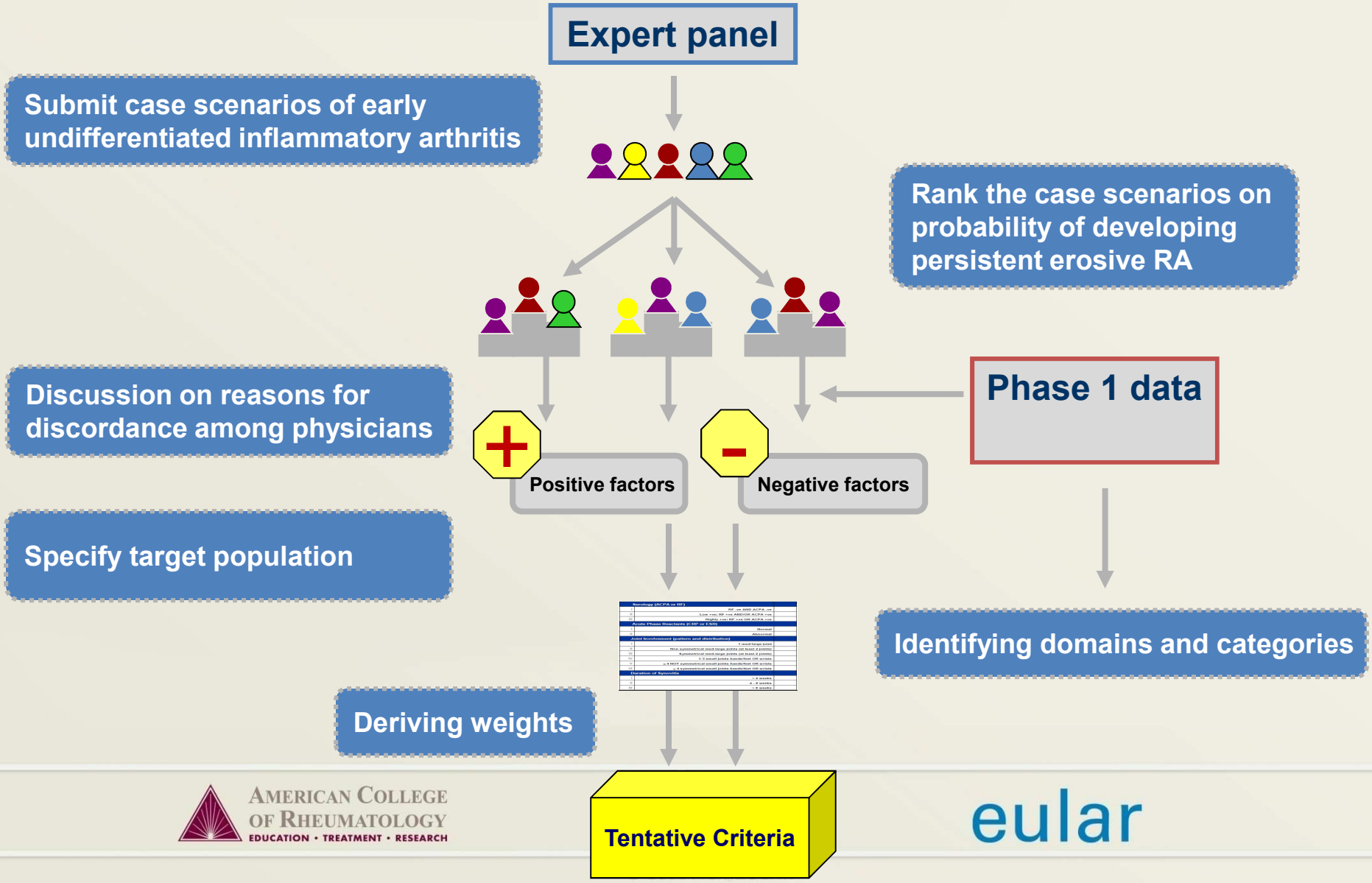
Specify target population



Identifying domains and categories

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Phase 2: Overview



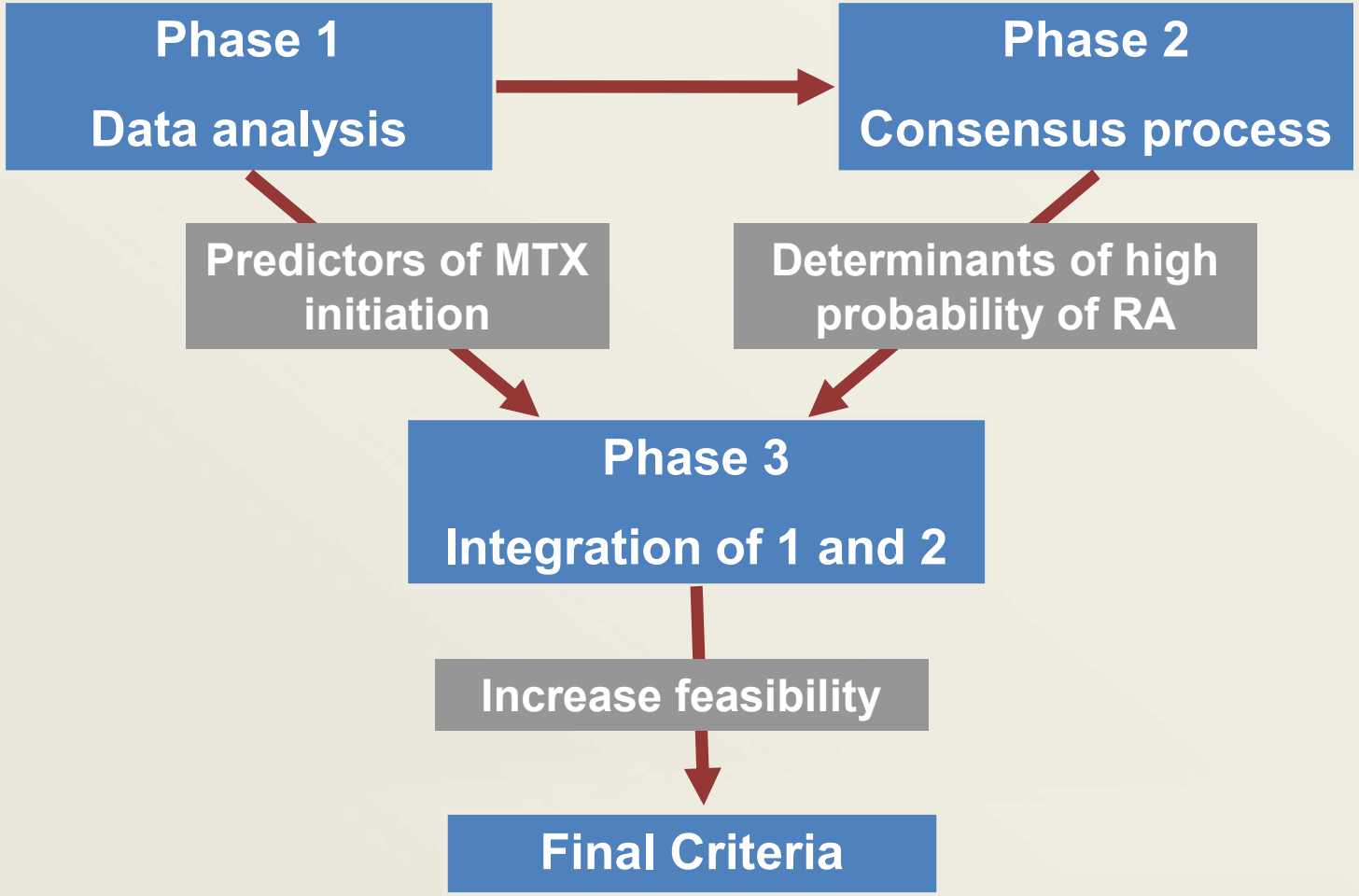
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Phase 2: Results

	Tentative scoring
JOINT INVOLVEMENT	
1 medium-large	0
>1-10 medium-large, asymmetric	10.2
>1-10 medium-large, symmetric	16.1
1-3 small	21.2
4-10 small	28.8
>10, including at least one small joint	50.8
SEROLOGY (RF or ACPA)	
0 (<ULN)	0
+ (ULN to ≤3xULN)	22.0
++ (>3xULN)	33.9
ACUTE PHASE REACTANTS (ESR or CRP)	
Normal	0
Abnormal	5.9
DURATION OF SYMPTOMS	
<6 weeks	0
≥6 weeks	9.3

Phases of the Project



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Phase 3

Integration of Findings from Phases 1 and 2

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Optimizing Feasibility

	Exact (0-100)		
JOINT INVOLVEMENT			
1 medium-large	0		
>1-10 medium-large, asymmetric	10.2		
>1-10 medium-large, symmetric	16.1		
1-3 small	21.2		
4-10 small	28.8		
>10, including at least one small joint	50.8		
SEROLOGY (RF or ACPA)			
0 (<ULN)	0		
+ (ULN to ≤3xULN)	22.0		
++ (>3xULN)	33.9		
ACUTE PHASE REACTANTS (ESR or CRP)			
Normal	0		
Abnormal	5.9		
SYMPTOM DURATION			
<6 weeks	0		
≥6 weeks	9.3		

Optimizing Feasibility

	Exact (0-100)	Rescaled (0-10)	
JOINT INVOLVEMENT			
1 medium-large	0	0	
>1-10 medium-large, asymmetric	10.2	1.02	
>1-10 medium-large, symmetric	16.1	1.61	
1-3 small	21.2	2.12	
4-10 small	28.8	2.88	
>10, including at least one small joint	50.8	5.08	
SEROLOGY (RF or ACPA)			
0 (<ULN)	0	0	
+ (ULN to ≤3xULN)	22.0	2.20	
++ (>3xULN)	33.9	3.39	
ACUTE PHASE REACTANTS (ESR or CRP)			
Normal	0	0	
Abnormal	5.9	0.59	
SYMPTOM DURATION			
<6 weeks	0	0	
≥6 weeks	9.3	0.93	

Optimizing Feasibility

	Exact (0-100)	Rescaled (0-10)	Rounded to 0.5 (0-10)
JOINT INVOLVEMENT			
1 medium-large	0	0	0
>1-10 medium-large, asymmetric	10.2	1.02	1
>1-10 medium-large, symmetric	16.1	1.61	1.5
1-3 small	21.2	2.12	2
4-10 small	28.8	2.88	3
>10, including at least one small joint	50.8	5.08	5
SEROLOGY (RF or ACPA)			
0 (<ULN)	0	0	0
+ (ULN to ≤3xULN)	22.0	2.20	2
++ (>3xULN)	33.9	3.39	3.5
ACUTE PHASE REACTANTS (ESR or CRP)			
Normal	0	0	0
Abnormal	5.9	0.59	0.5
SYMPTOM DURATION			
<6 weeks	0	0	0
≥6 weeks	9.3	0.93	1

Final Criteria

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Target Population of the Criteria

Two requirements:

(1) Patient with at least one joint with definite clinical synovitis (swelling)

(2) Synovitis is not better explained by "another disease"

Differential diagnoses differ in patients with different presentations.

If unclear about the relevant differentials, an expert rheumatologist should be consulted.

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2010 ACR/EULAR Classification Criteria for RA

JOINT DISTRIBUTION (0-5)	
SEROLOGY (0-3)	
SYMPTOM DURATION (0-1)	
ACUTE PHASE REACTANTS (0-1)	

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2010 ACR/EULAR Classification Criteria for RA

JOINT DISTRIBUTION (0-5)	
1 large joint	0
2-10 large joints	1
1-3 small joints (large joints not counted)	2
4-10 small joints (large joints not counted)	3
>10 joints (at least one small joint)	5
SEROLOGY (0-3)	
SYMPTOM DURATION (0-1)	
ACUTE PHASE REACTANTS (0-1)	

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4-10 small joints (large joints not counted)	3
>10 joints (at least one small joint)	5
SEROLOGY (0-3)	
Negative RF AND negative ACPA	0
Low positive RF OR low positive ACPA	2
High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
ACUTE PHASE REACTANTS (0-1)	

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SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	

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High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

≥6 = definite RA

What if the score is <6?

Patient might fulfill the criteria…

→ **Prospectively** over time (cumulatively)

→ **Retrospectively** if data on all four domains have been adequately recorded in the past

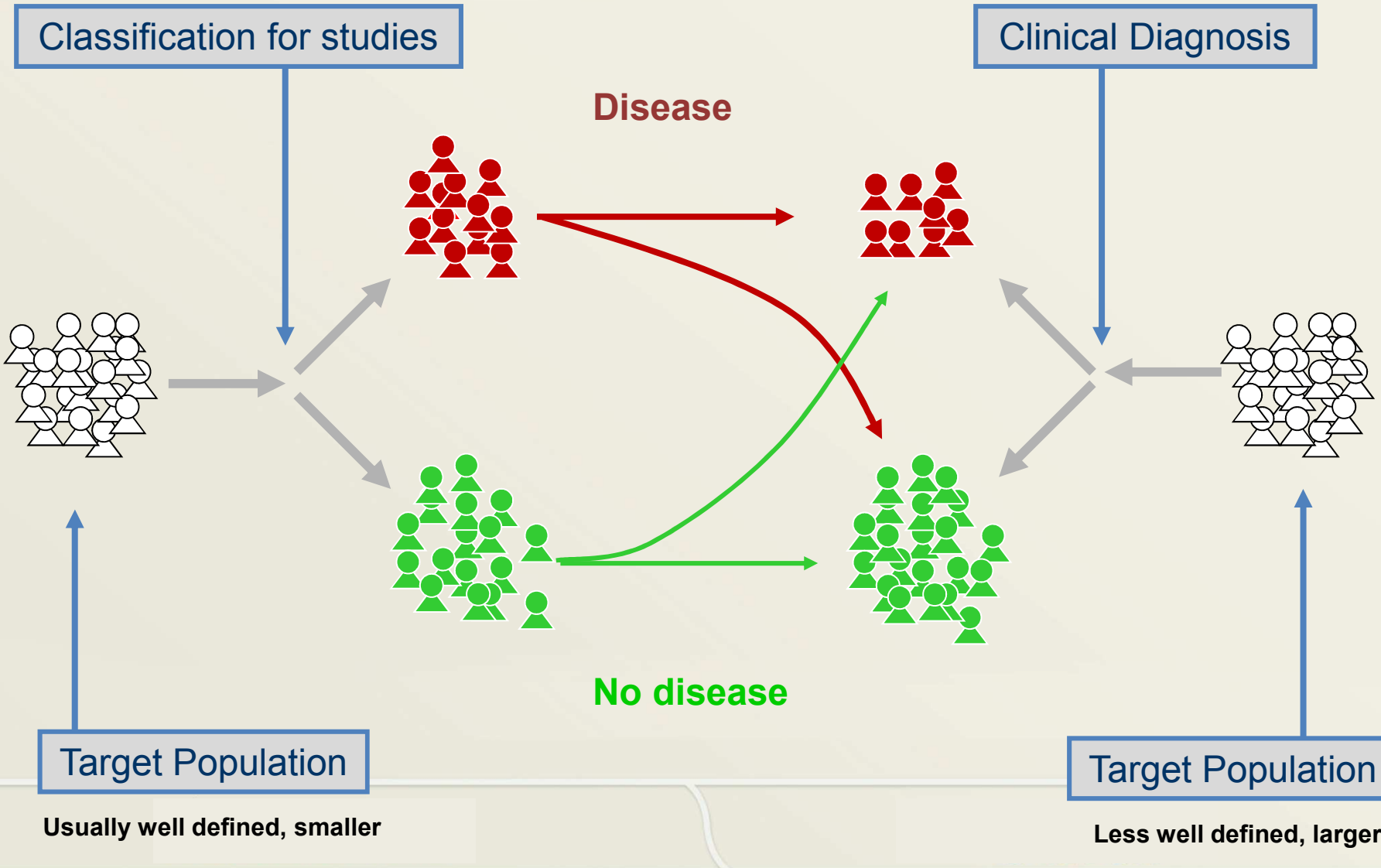
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Classification vs. Diagnosis

- We **don't have diagnostic criteria** for RA
- Typically in rheumatic diseases, criteria are labeled as **"classification" criteria**
  - These are helpful in defining homogeneous treatment populations for study purposes
- A **clinical "diagnosis"** has to be established by the physician (rheumatologist)
  - It includes many more aspects than can be included in formal criteria
  - Formal classification criteria might be a guide to establish a clinical diagnosis

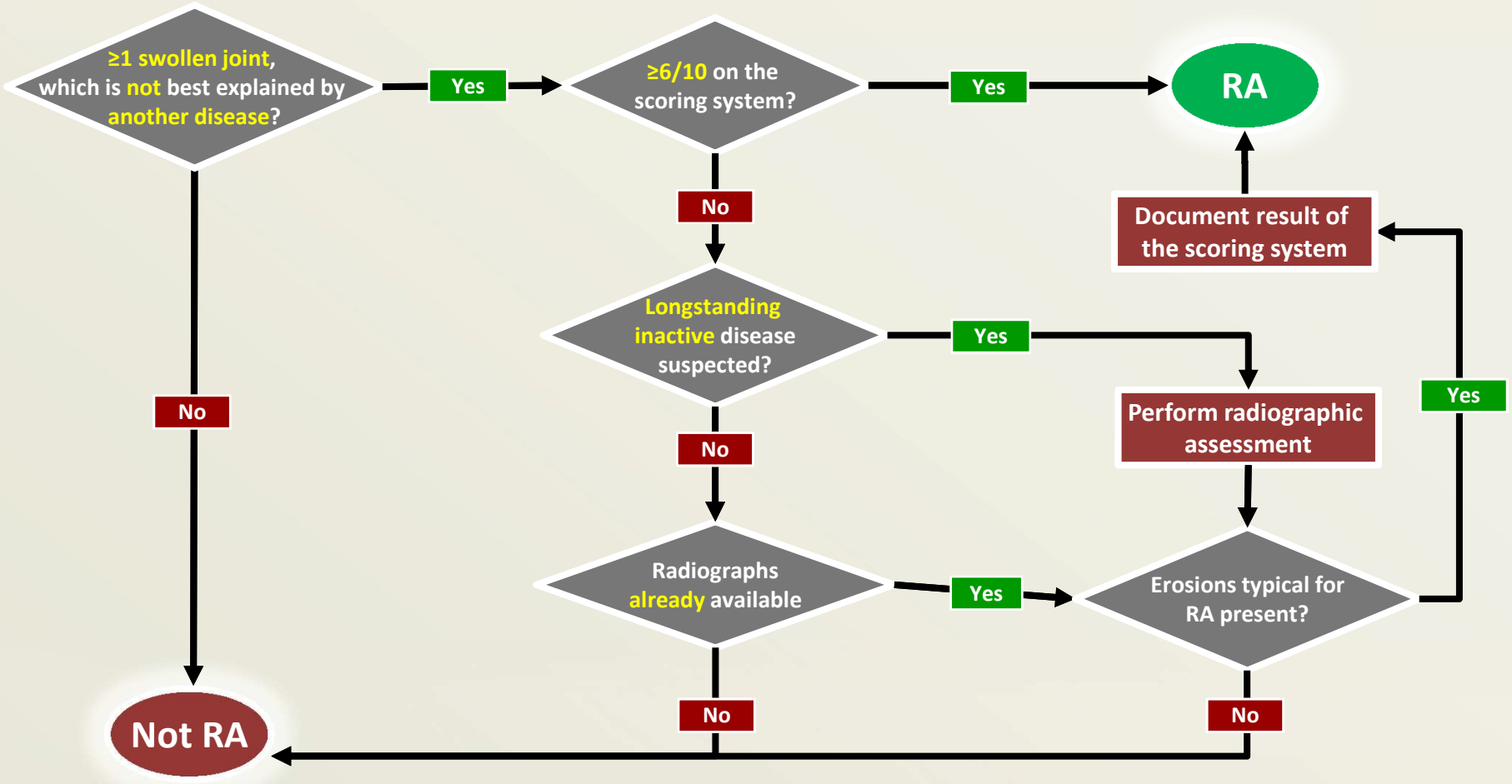
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Classification vs. Diagnosis



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Algorithm to Classification of RA Including Radiographs



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Summary: Radiographic Assessment

WHEN TO PERFORM

GENERAL PRINCIPLES

•Radiographs are **not required** in the ACR/EULAR 2010 classification criteria

•Radiographs **should not be taken** for the mere purpose of classification

EXCEPTIONS

1.Radiographs **should be taken** in the **unclassified** patient in whom **longstanding inactive** disease is suspected (likely failed classification falsely)

2.If radiographs **are already available** in an early arthritis patient, their information can be used for classification purposes.
(e.g., radiographs taken by GP before referral)

HOW TO USE

- **The presence of typical erosions allow classification of RA even without fulfillment of the scoring system**
- The scoring result should nevertheless be documented in clinical studies/trials
- Currently, there is no exact definition of "typical erosions"
- There is work in progress to develop the respective definitions

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Definitions

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Definitions

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Negative RF AND negative ACPA	0
Low positive RF OR low positive ACPA	2
High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

≥6 = definite RA

Definition of "JOINT INVOLVEMENT"

- Any swollen **or** tender joint (excluding DIP of hand and feet, 1st MTP, 1st CMC)
- Additional evidence from **MRI / US** may be used for confirmation of the clinical findings

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High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

≥6 = definite RA

Definition of "SMALL JOINT"

MCP, PIP, MTP 2-5, thumb IP, wrist

NOT: DIP, 1st CMC, 1st MTP

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SEROLOGY (0-3)	
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High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

Definition of "LARGE JOINT"

Shoulder, elbow, hip, knee, ankles

≥6 = definite RA

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High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

≥6 = definite RA

Definition of "<u>>10 JOINTS</u>"

- At least **one** small joint
- **Additional joints** include: temporomandibular, sternoclavicular, acromioclavicular, and others (reasonably expected in RA)

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<6 weeks	0
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ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
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≥6 = definite RA

Definition of "SEROLOGY"

Negative: ≤*ULN* (for the respective lab)

Low positive: >*ULN but* ≤*3xULN*

High positive: >*3xULN*

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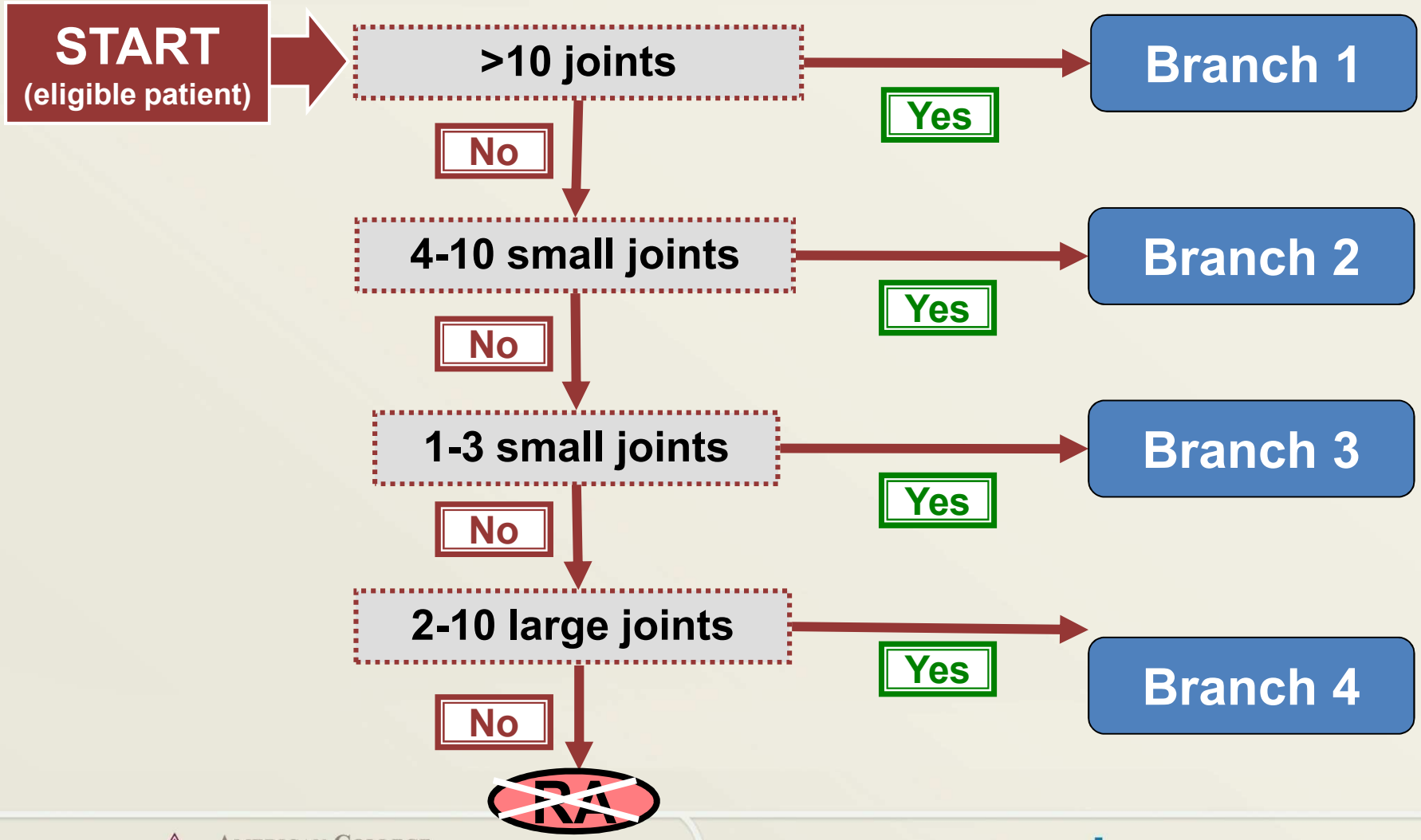
≥6 = definite RA

Definition of "SYMPTOM DURATION"

Refers to the patient's self-report on the maximum duration of signs and symptoms of any joint that is clinically involved at the time of assessment.

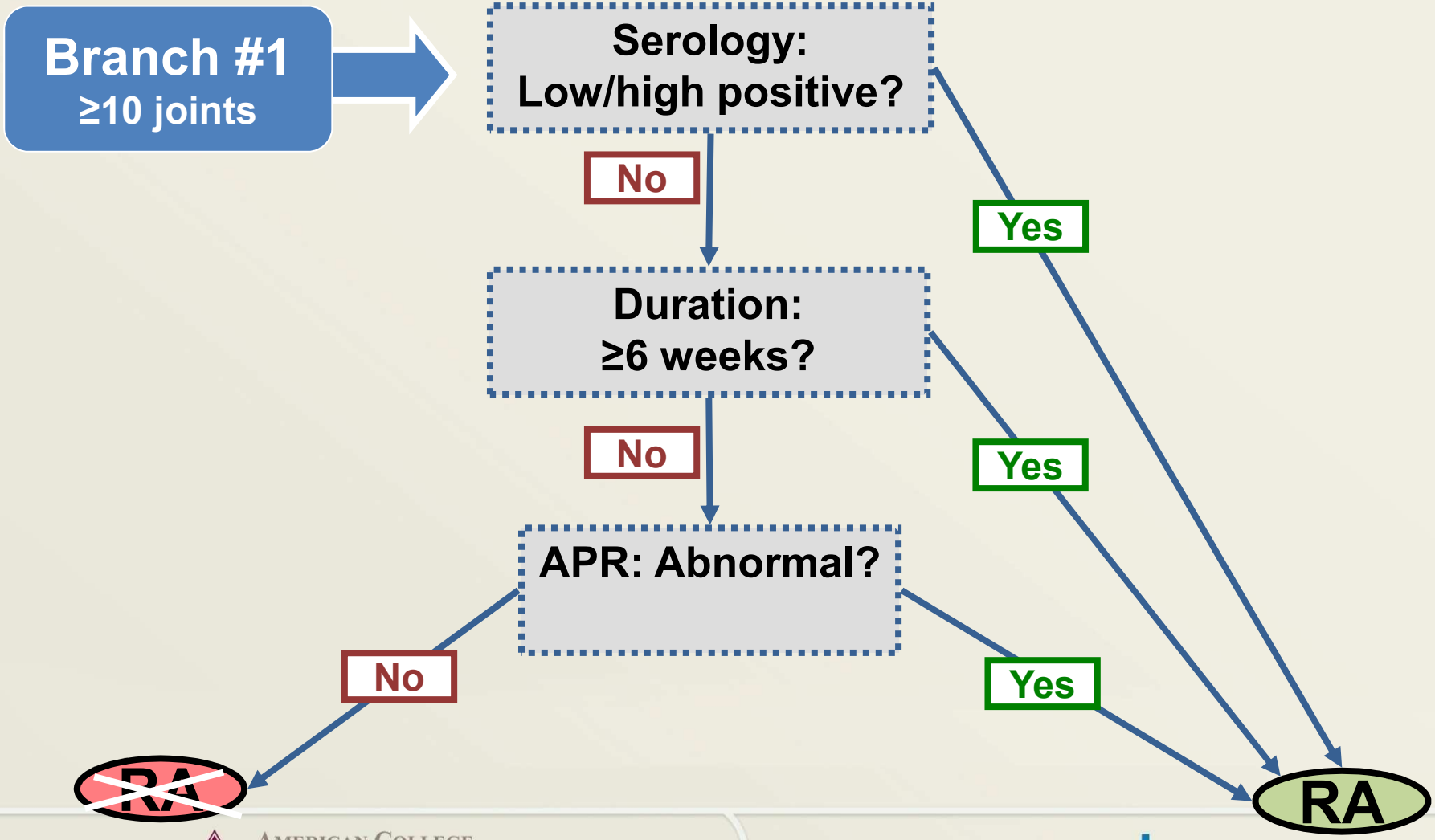
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Algorithm for Classification



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Branch #1: Polyarticular Presentation

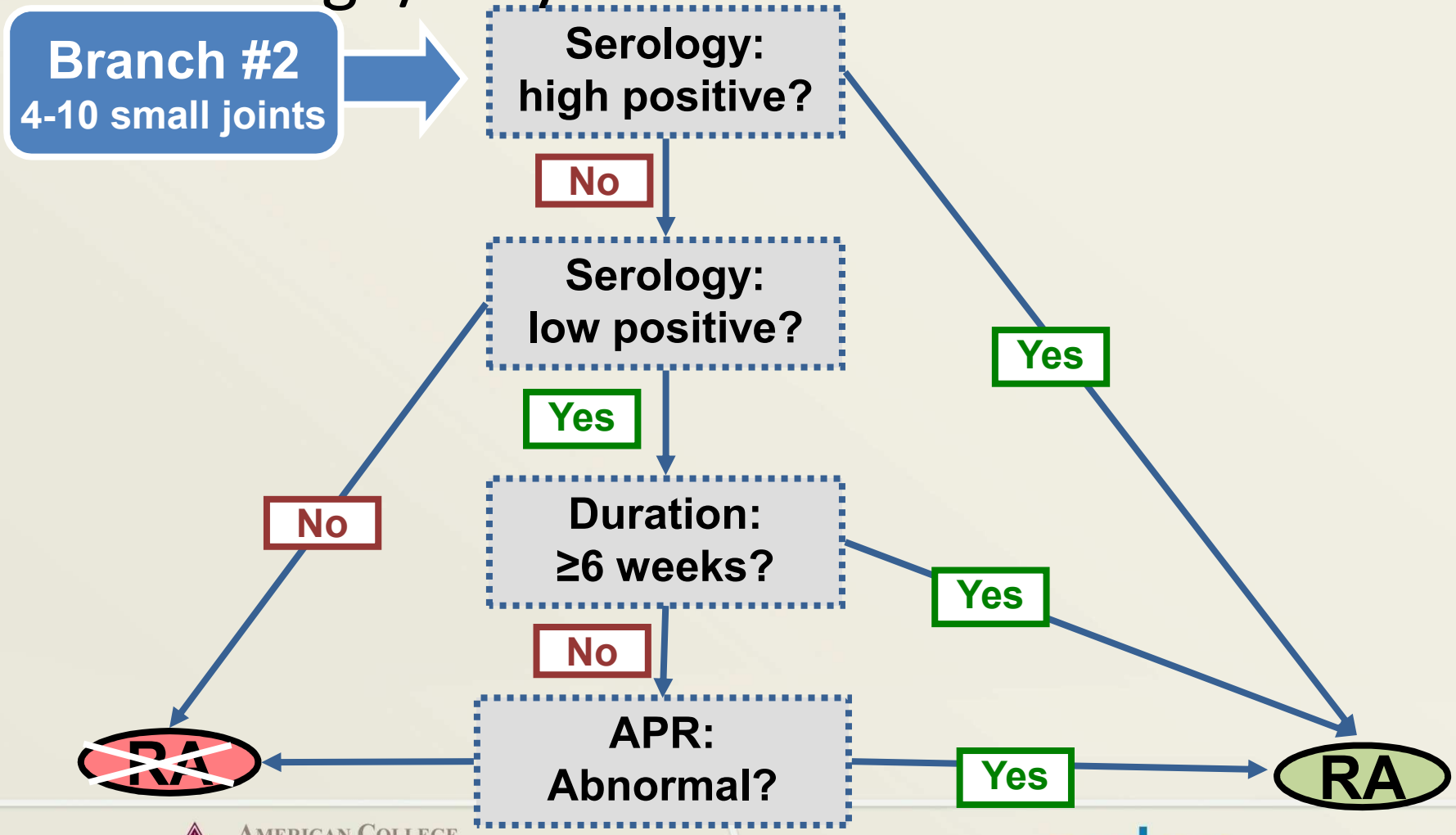


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Branch #2: Presentation with Oligo/Polyarticular Small Joints

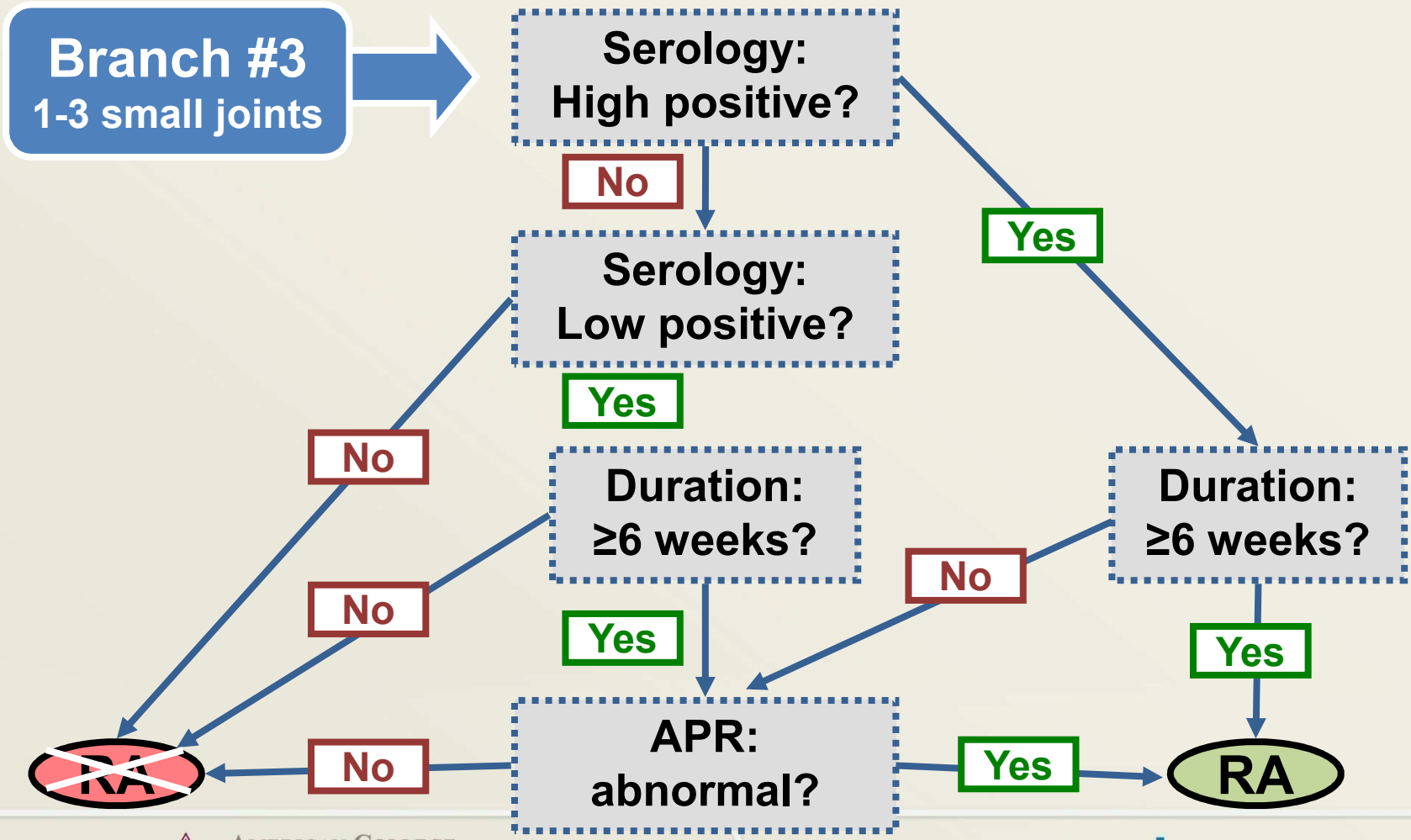


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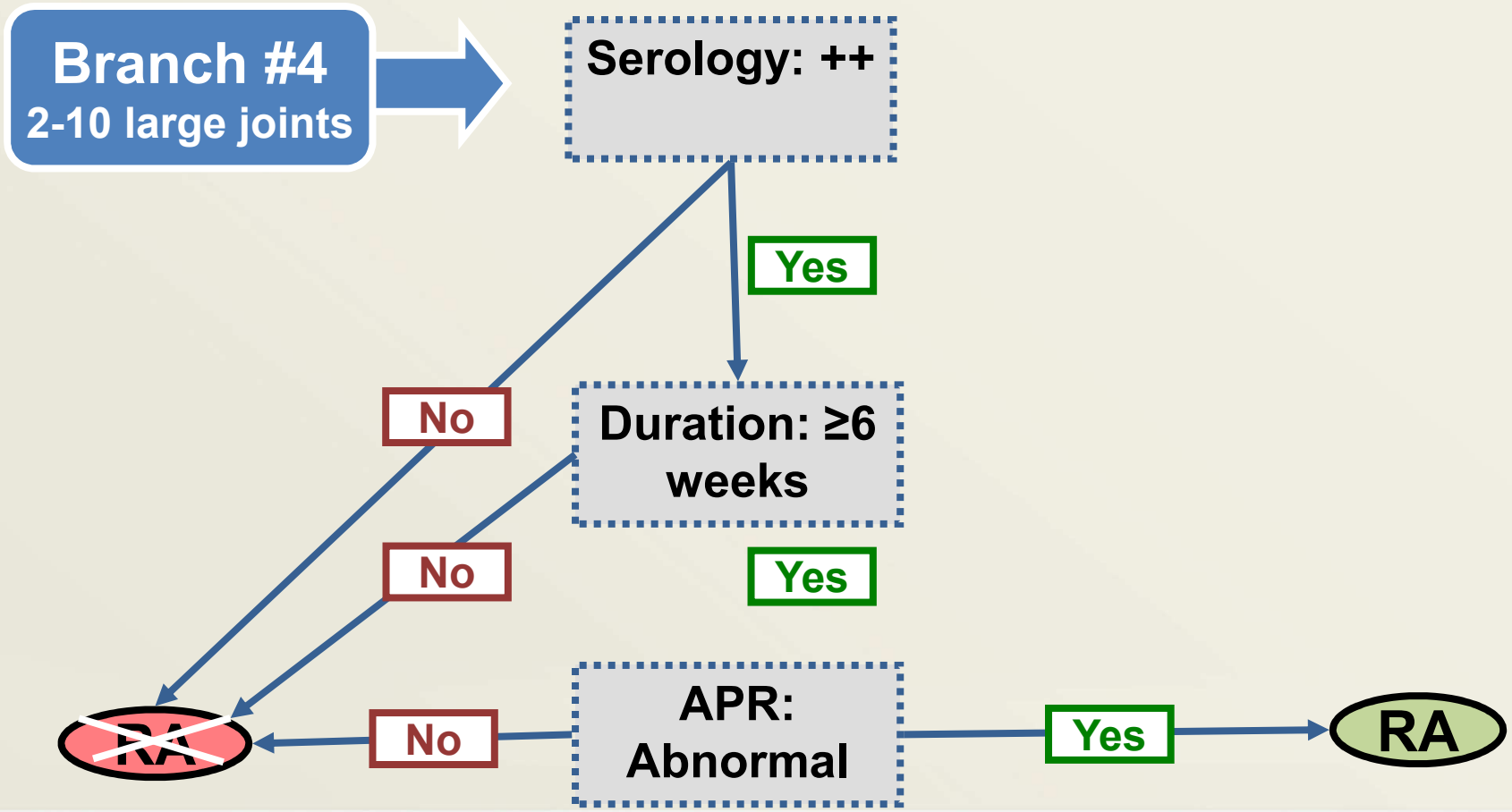
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Branch #3: Presentation with Mono/Oligoarticular Small Joints

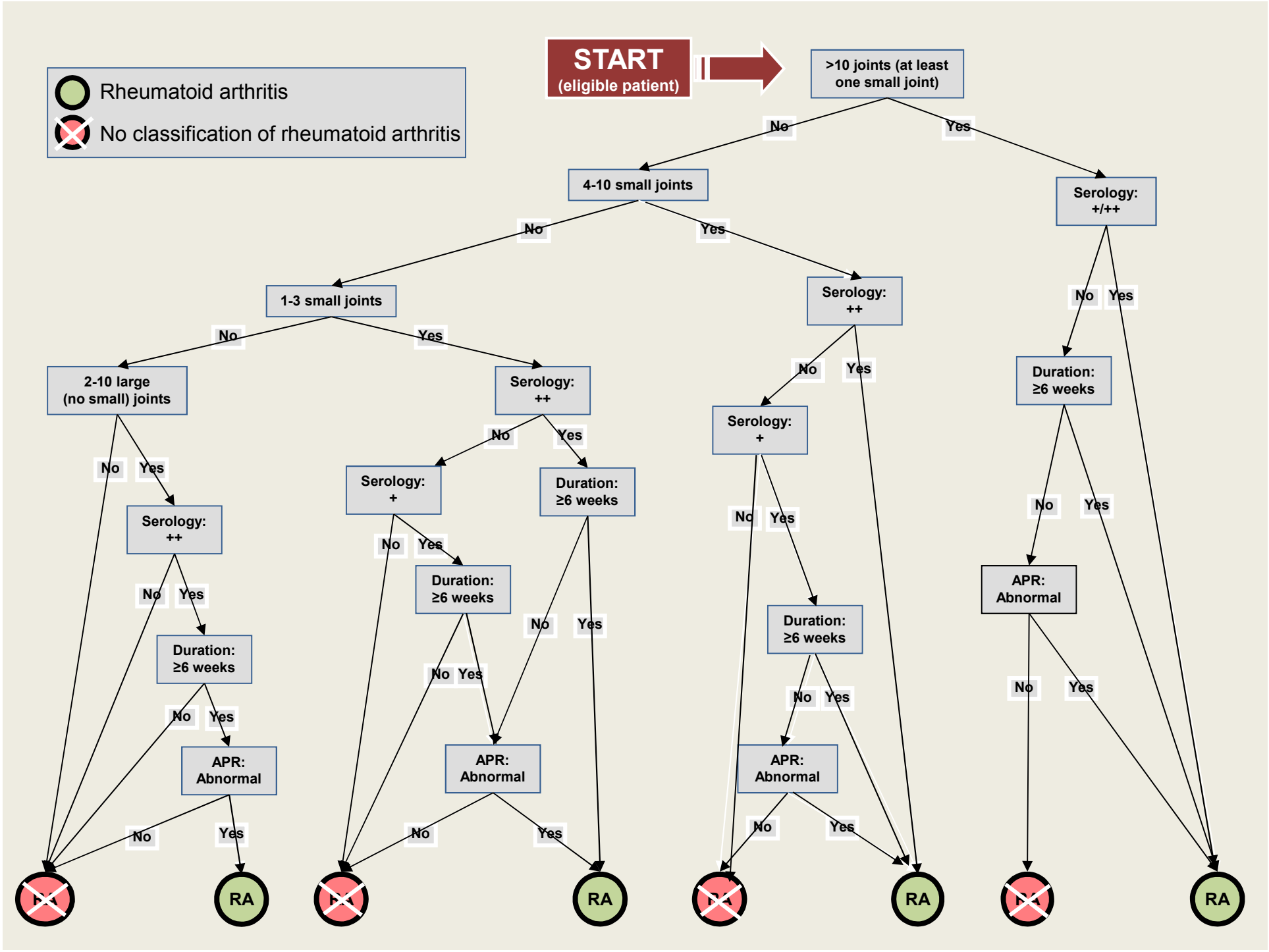


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Branch #3: Presentation with Oligo/Polyarticular Large Joints



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Rheumatoid arthritis
No classification of rheumatoid arthritis
START
(eligible patient)
>10 joints (at least one small joint)
No
Yes
4-10 small joints
Serology: +/++
No
Yes
1-3 small joints
Serology: ++
Duration: ≥6 weeks
2-10 large (no small) joints
Serology: ++
Serology: +
Duration: ≥6 weeks
Serology: +
Duration: ≥6 weeks
APR: Abnormal
APR: Abnormal
APR: Abnormal
RA

Example: False Positive Classification

JOINTS DISTRIBUTION (0-5)	
1 large joint	0
2-10 large joints	1
1-3 small joints (large joints not counted)	2
4-10 small joints (large joints not counted)	3
>10 joints (at least one small joint)	5
SEROLOGY (0-3)	
Negative RF AND negative ACPA	0
Low positive RF OR low positive ACPA	2
High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

CASE SCENARIO

Inflammatory Osteoarthritis

- **One clinically inflamed OA joint (PIP 3 right hand)**
- **Tenderness of all DIPs, PIPs, thumb IPs, CMC 1, and knees**
- **Seronegative**
- **Long standing disease**
- **Normal acute phase**

→ If OA is clinically apparent, then this patient would not be in the target population of the criteria

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≥6 = definite RA

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Example: False Negative Classification

JOINTS DISTRIBUTION (0-5)	
1 large joint	0
2-10 large joints	1
1-3 small joints (large joints not counted)	2
4-10 small joints (large joints not counted)	3
>10 joints (at least one small joint)	5
SEROLOGY (0-3)	
Negative RF AND negative ACPA	0
Low positive RF OR low positive ACPA	2
High positive RF OR high positive ACPA	3
SYMPTOM DURATION (0-1)	
<6 weeks	0
≥6 weeks	1
ACUTE PHASE REACTANTS (0-1)	
Normal CRP AND normal ESR	0
Abnormal CRP OR abnormal ESR	1

CASE SCENARIO

Early seronegative RA

- **Swollen and tender MCP 1-3 on both sides**
- **Seronegative**
- **2 weeks duration**
- **Elevated CRP levels**

→ This patient might fulfill the criteria at a subsequent visit (be classified prospectively)

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≥6 = definite RA

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Important Notes

- **Criteria are classification criteria NOT diagnostic criteria**
  - In clinical practice they may inform the physician's diagnosis
- **For the purpose of classification, radiographs should only be performed**
  - For patients with longstanding inactive ("burnt out") disease, who are NOT yet formally classified or diagnosed, and who would fail to classify as RA according to the scoring system, given their joint inactivity
  - The term "erosions, typical for RA" still needs to be precisely defined (size, site, number)
- **No exhaustive list of exclusions is defined**
  - Differential diagnosis is responsibility of the physician (influenced by age, gender, population, etc.)
  - Limits false positive classification

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Future Prospects

- 87-97% of patients started on MTX within one year were positively classified as RA in independent cohorts at baseline
- Formal external validation studies are ongoing
  - Comparing proportions fulfilling ACR 1987 and ACR/EULAR 2010 criteria
  - Identifying sensitivity, specificity, PPV, NPV etc. in independent settings

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Summary

- New classification criteria for RA have been established by an international task force
- Criteria are meant to be used for patients with clinical synovitis in at least one joint
- The classification criteria are not diagnostic criteria, but they can inform the diagnosis, which ultimately has to be made by the rheumatologist
- Validation in independent cohorts is already ongoing

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