**70 ANNI DI REUMATOLOGIA ALLE MOLINETTE**

**Starhotels Majestic,**
**corso Vittorio Emanuele II 54, Torino**

**11-12 ottobre 2019**

# Aspetti terapeutici delle Spondiloartriti

Dr Fabrizio Cantini

UOC Reumatologia - Prato

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# SpA: licensed therapies

- NSAIDs
- SSZ, MTX
- Anti-TNFs
- Anti-IL17

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American College of Rheumatology
Empowering Rheumatology Professionals

SPECIAL ARTICLE

# 2019 Update of the American College of Rheumatology/ Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis

Michael M. Ward,[1] Atul Deodhar,[2] Lianne S. Gensler,[3] Maureen Dubreuil,[4] David Yu,[5] Muhammad Asim Khan,[6] Nigil Haroon,[7] David Borenstein,[8] Runsheng Wang,[9] Ann Biehl,[1] Meika A. Fang,[10] Grant Louie,[11] Vikas Majithia,[12] Bernard Ng,[13] Rosemary Bigham,[14] Michael Pianin,[15] Amit Aakash Shah,[16] Nancy Sullivan,[17] Marat Turgunbaev,[16] Jeff Oristaglio,[17] Amy Turner,[16] Walter P. Maksymowych,[18] and Liron Caplan[19]

| | | |
|---|---|---|
| 1. We strongly recommend treatment with NSAIDs over no treatment with NSAIDs.† | Low | 2 |
| 2. We conditionally recommend continuous treatment with NSAIDs over on-demand treatment with NSAIDs. | Low to moderate | 1 |
| 3. We do not recommend any particular NSAID as the preferred choice.† | Low to moderate | 3 |

| | | |
|---|---|---|
| 6. In adults with active AS despite treatment with NSAIDs, we strongly recommend treatment with TNFi over no treatment with TNFi. | High | 6 |
| 7. We do not recommend any particular TNFi as the preferred choice. | Moderate | 5 |

| | | |
|---|---|---|
| 11. In adults with active AS despite treatment with NSAIDs and who have contraindications to TNFi, we conditionally recommend treatment with secukinumab or ixekizumab over treatment with sulfasalazine, methotrexate, or tofacitinib. | Low | 8 |
| 12. In adults with active AS despite treatment with the first TNFi used, we conditionally recommend treatment with secukinumab or ixekizumab over treatment with a different TNFi in patients with primary nonresponse to TNFi. | Very low | 10 |

# Terapie di seconda linea approvate per la PsA e SpA

# Axial-SpA
# Anti-TNF choice: efficacy and safety

- **Anti-TNF efficacy in up to 70% of AS patients**
- Absence of head to head trials comparing the efficacy
- Head to head trial IFX vs bio-IFX: no differences in efficacy in AS (Park W, et al. Ann Rheum Dis 2013)
- Efficacy of ADA, ETN, IFX, bio-IFX, GOL, and CTP for the treatment of AS, and non-rx-Ax SpA has been evaluated by indirect comparison in several systematic reviews and meta-analyses: no significant differences with a trend toward a better efficacy of IFX and bio-IFX (McLeod C, et al. Health Technol Assess. 2007; Migliore A, et al. J Med Econ. 2012; Shu T, et al. Clin Exp Rheumatol 2013; Baji P, et al. Eur J Health Econ 2014; Migliora A, et al. Clin Drug Investig 2015; Singh JA, et al. Cochrane Database Syst Rev. 2011; Maxwell LJ, et al. Cochrane Database Syst Rev. 2015)
- **Safety:** no significant differences have been observed among anti-TNF drugs, though a trend toward a better safety profile of ETN in terms of infection and TB risk (Ramiro S, et al. Ann Rheum Dis 2014; Cantini F, et al. Autoimmun Rev 2015)

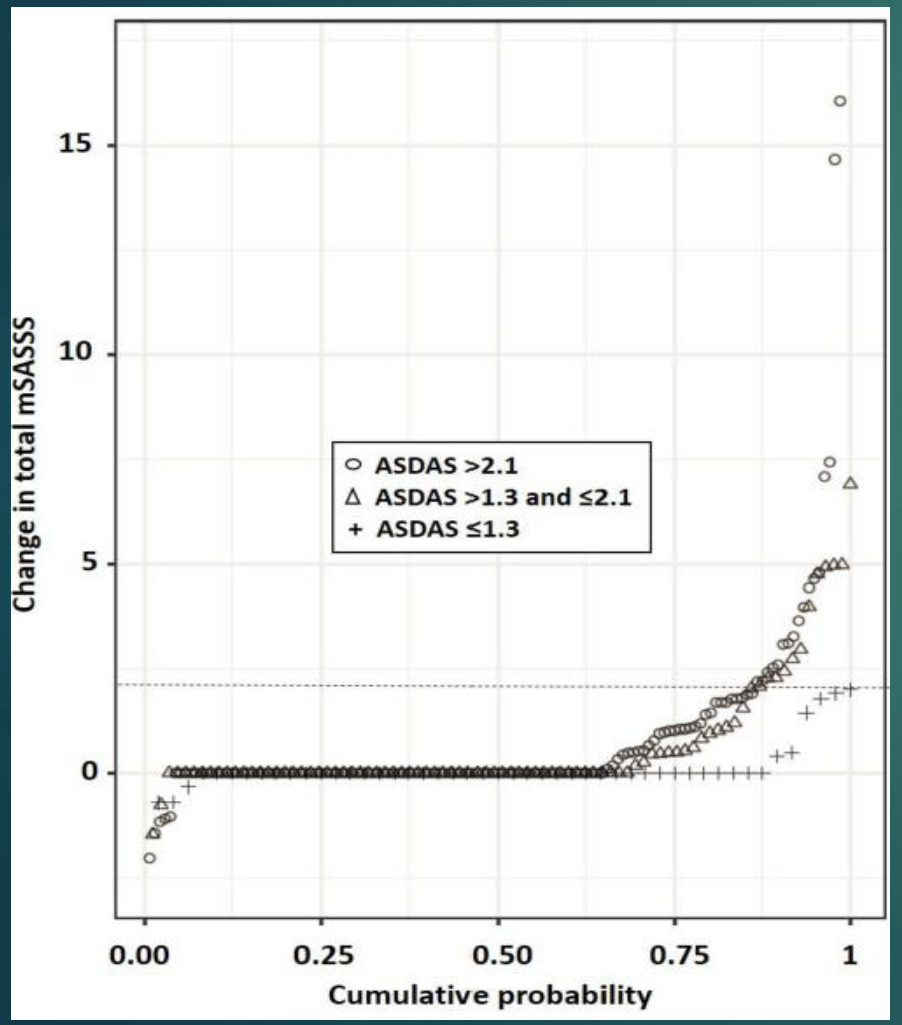
# Biologici anti-TNF

| Farmaco | Target | Posologia | Indicazioni |
|---|---|---|---|
| Adalimumab | TNFa | 40 mg/sc/2 sett. | AR, AP, SA |
| *Adalimumab biosimil.* | TNFa | 40 mg/sc/2 sett. | AR, AP, SA |
| Certolizumab | TNFa | 200 mg/sc/2 sett. | AR (AP, SA) |
| Etanercept | TNFa | 50 mg/sc/sett. | AR, AP, SA |
| *Etanercept biosimil.* | TNFa | 50 mg/sc/sett. | AR, AP, SA |
| Golimumab | TNFa | 50 mg/sc/mese | AR, AP, SA |
| Infliximab | TNFa | 3-5 mg/Kg/ev/8 sett. | AR, AP, SA |
| *Infliximab biosimil.* | TNFa | 3-5 mg/Kg/ev/8 sett. | AR, AP, SA |

- Efficacia nel 60-70% dei pazienti con SpA, AP
- Anti-TNF monoclonali efficaci sulle manifestazioni extra-articolari della SpA
- *Rischio infettivo: basso-moderato*; il rischio si riduce nel tempo
- *Rischio di riattivazione di TB latente aumentato*
- Rischio neoplastico non aumentato
- Evidenza di prevenzione degli eventi cardio-vascolari ischemici

# TNF blockers inhibit spinal radiographic progression in ankylosing spondylitis by reducing disease activity: results from the Swiss Clinical Quality Management cohort

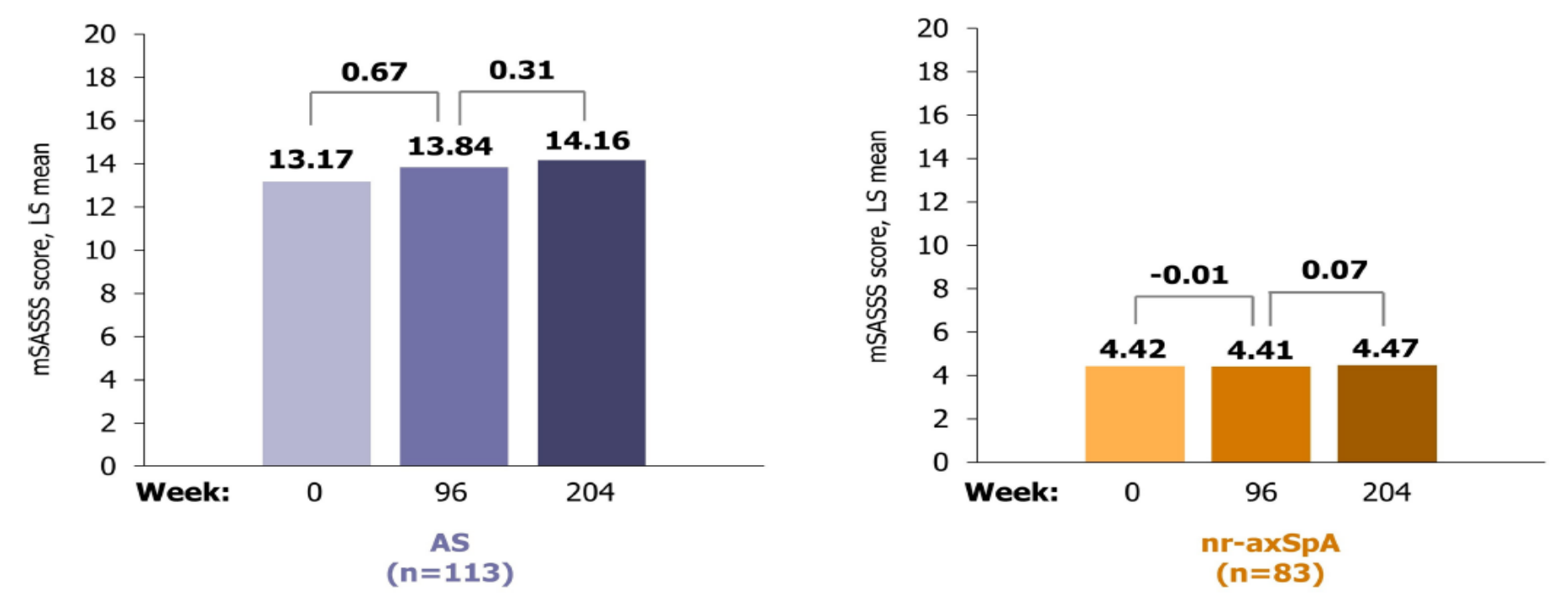
**Molnar C, et al. Ann Rheum Dis 2018**




- ✓ Association between TNFi use and reduced risk of spinal structural damage, both in terms of mSASSS and new syndesmophyte formation.
- ✓ The odds of radiographic progression were nearly halved over the next 2 years in patients having started TNFi treatment before this 2-year interval.
- ✓ The impact of TNFi on spinal radiographic progression is mediated by its decreasing effect on disease activity (ASDAS, BASDAI or CRP).

# Limited radiographic progression and sustained reductions in MRI inflammation in patients with axial spondyloarthritis: 4-year imaging outcomes from the RAPID-axSpA phase III randomised trial

Van der Heijde D, et al. Ann Rheum Dis 2018




**AS: mean mSASSS change from baseline was 0.98**
**nr-axSpA : mean mSASSS change of 0.06**

# The effectiveness of a real life dose reduction strategy for tumour necrosis factor inhibitors in ankylosing spondylitis and psoriatic arthritis

Warren Fong[1,2,*], Chris Holroyd[3,4,*], Brian Davidson[3], Ray Armstrong[3], Nick Harvey[3,4], Elaine Dennison[3,4], Cyrus Cooper[3,4,5] and Christopher J. Edwards[1,3]

Rheumatology 2016;55:1837–1842

## Rheumatology key messages

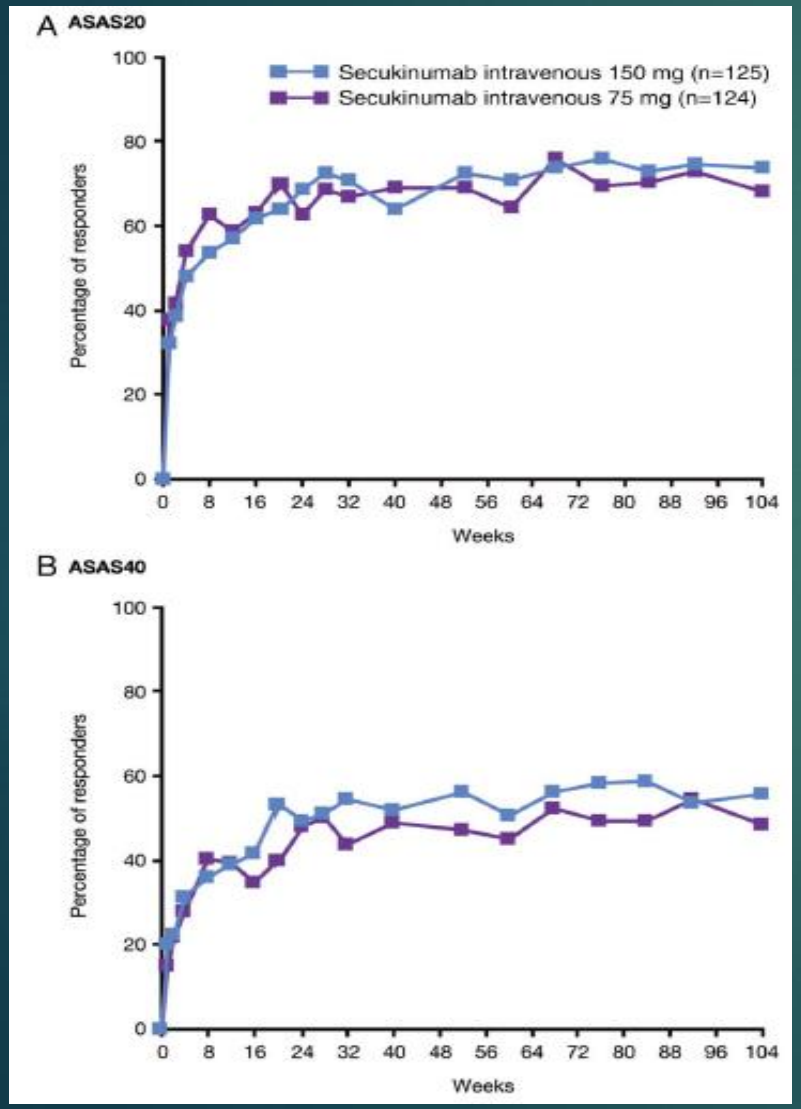
- Dose reduction may be successful in up to 60% of spondyloarthritis patients with longstanding and severe disease.
- Recapture of low disease activity appears possible for spondyloarthritis patients who fail dose reduction of TNFi therapy.

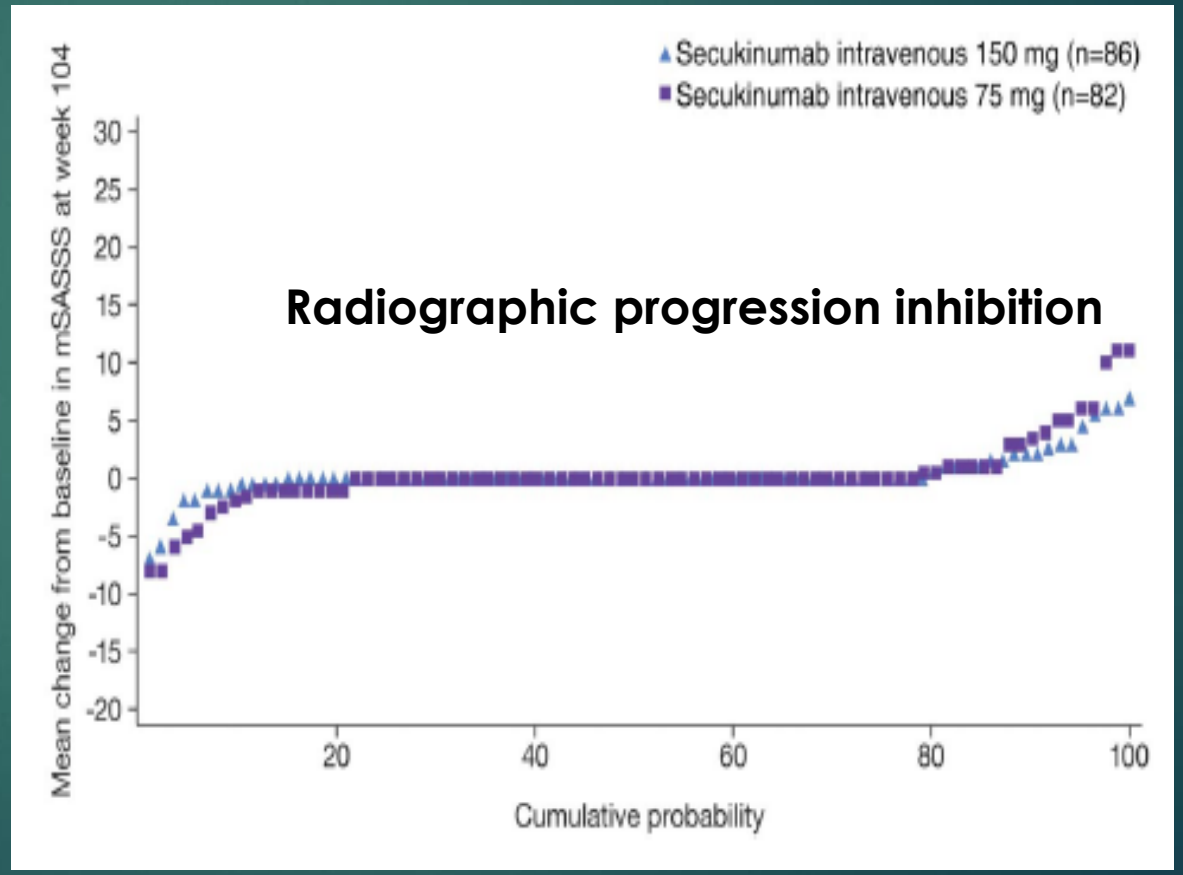
# Anti-IL-17 in Ankylosing spondylitis

# Effect of secukinumab on clinical and radiographic outcomes in ankylosing spondylitis: 2-year results from the randomised phase III MEASURE 1 study

Jürgen Braun,[1] Xenofon Baraliakos,[1] Atul Deodhar,[2] Dominique Baeten,[3] Joachim Sieper,[4] Paul Emery,[5] Aimee Readie,[6] Ruvie Martin,[6] Shephard Mpofu,[7] Hanno B Richards,[7] for the MEASURE 1 study group

Ann Rheum Dis 2016




**Radiographic progression inhibition**

# Ixekizumab, an interleukin-17A antagonist in the treatment of ankylosing spondylitis or radiographic axial spondyloarthritis in patients previously untreated with biological disease-modifying anti-rheumatic drugs (COAST-V): 16 week results of a phase 3 randomised, double-blind, active-controlled and placebo-controlled trial

Van der Heijde D, et al. Lancet 2018

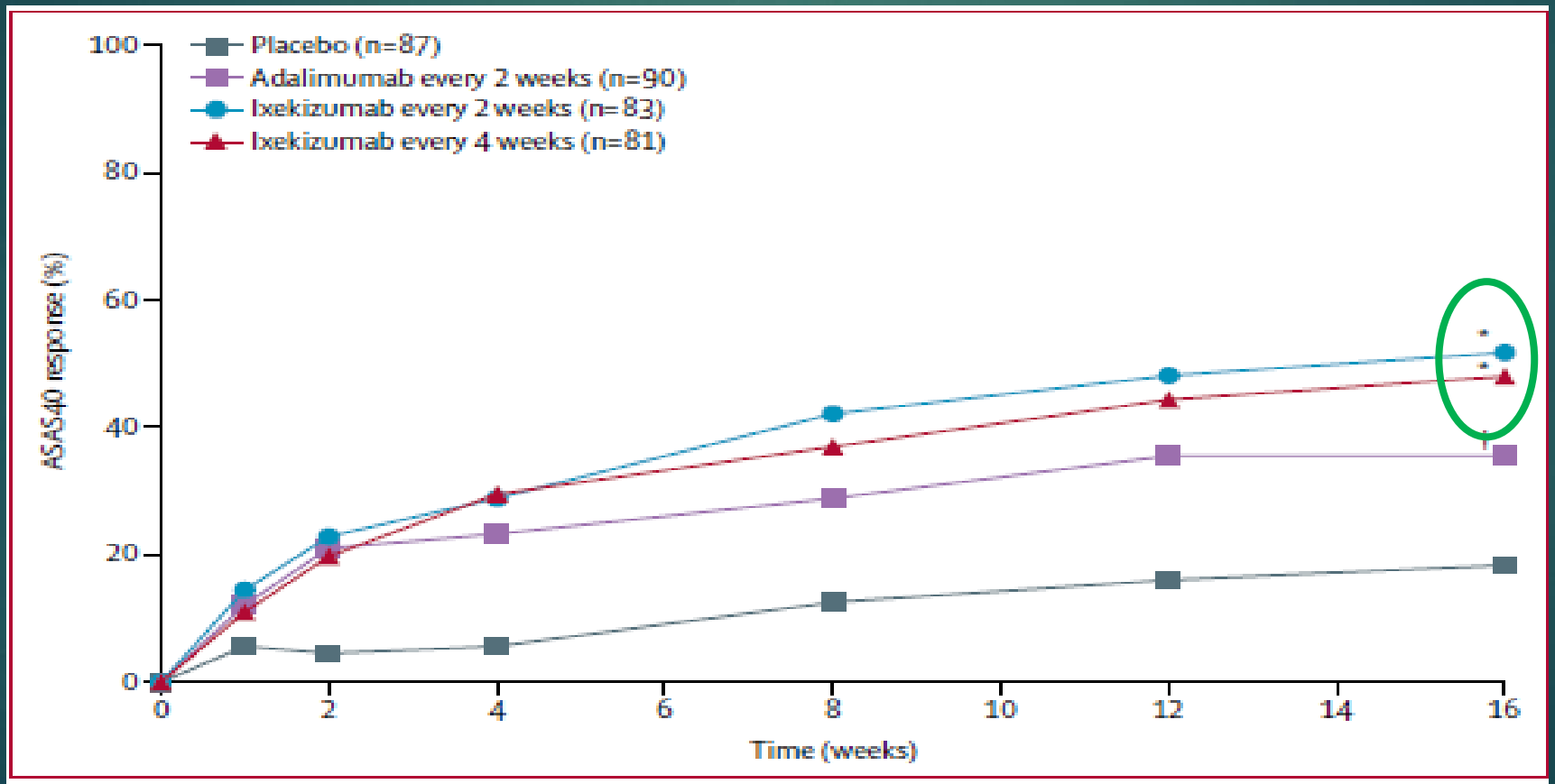



*Figure 2:* Proportion of patients achieving ASAS40 response through Week 16

# Secukinumab and Ixekizumab safety

**Table 3. Safety Profile during the 16-Week, Placebo-Controlled Induction Period of the MEASURE 1 and MEASURE 2 Studies.***

| Variable | MEASURE 1 | | MEASURE 2 | |
|---|---|---|---|---|
| | Secukinumab, Pooled Data (N=249) | Placebo (N=122) | Secukinumab, Pooled Data (N=145) | Placebo (N=74) |
| Exposure to study treatment — days | 113.2±13.2 | 109.2±22.7 | 110.1±15.8 | 107.6±22.4 |
| Any adverse event — no. of patients (%) | 170 (68) | 68 (56) | 89 (61) | 47 (64) |
| Death — no. of patients (%) | 0 | 1 (<1)† | 1 (<1)‡ | 0 |
| Serious adverse event — no. of patients (%)‡ | 5 (2) | 5 (4) | 8 (6) | 3 (4) |
| Discontinuation of study treatment because of any adverse event — no. of patients (%) | 3 (1) | 5 (4) | 7 (5) | 4 (5) |
| Infection or infestation — no. of patients (%)§ | 75 (30) | 15 (12) | 46 (32) | 20 (27) |
| Common adverse events — no. of patients (%)¶ | | | | |
| Nasopharyngitis | 30 (12) | 9 (7) | 14 (10) | 3 (4) |
| Dyslipidemia | 24 (10) | 6 (5) | 2 (1) | 1 (1) |
| Headache | 20 (8) | 7 (6) | 6 (4) | 6 (8) |
| Adverse events of special interest — no. of patients (%) | | | | |
| Candida infection | 1 (<1) | 0 | 1 (<1) | 0 |
| Crohn's disease | 1 (<1) | 0 | 1 (<1) | 0 |
| Major adverse cardiac event, adjudicated | 0 | 0 | 1 (<1)‡ | 0 |
| Neutropenia, grade 3 or 4 | 0 | 0 | 0 | 0 |

| | Placebo (n=86) | Adalimumab Q2W (n=90) | Ixekizumab Q2W (n=83) | Ixekizumab Q4W (n=81) |
|---|---|---|---|---|
| Treatment-emergent adverse events | 34 (40%) | 44 (49%) | 36 (43%) | 34 (42%) |
| Mild | 22 (26%) | 28 (31%) | 28 (34%) | 22 (27%) |
| Moderate | 11 (13%) | 14 (16%) | 6 (7%) | 12 (15%) |
| Severe | 1 (1%) | 2 (2%) | 2 (2%) | 0 |
| Discontinuation due to any adverse event | 0 | 1 (1%) | 3 (4%) | 0 |
| Serious adverse event | 0 | 3 (3%) | 1 (1%) | 1 (1%) |
| Death | 0 | 0 | 0 | 0 |
| Common adverse events* | | | | |
| Nasopharyngitis | 6 (7%) | 6 (7%) | 5 (6%) | 6 (7%) |
| Upper respiratory tract infection | 4 (5%) | 2 (2%) | 4 (5%) | 7 (9%) |
| Adverse events of special interest | | | | |
| Neutropenia† | | | | |
| Grade 1 | 2 (2%) | 18 (20%) | 8 (10%) | 6 (8%) |
| Grade 2 | 1 (1%) | 3 (3%) | 3 (4%) | 2 (3%) |
| Grade 3 | 0 | 1 (1%) | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Hepatic | 1 (1%) | 2 (2%) | 1 (1%) | 1 (1%) |
| Infections | 13 (15%) | 19 (21%) | 17 (20%) | 16 (20%) |
| Serious infections | 0 | 1 (1%) | 1 (1%) | 1 (1%) |
| *Candida* infections | 0 | 1 (1%) | 0 | 0 |
| Reactivated tuberculosis | 0 | 0 | 0 | 0 |
| Injection site reactions | 4 (5%) | 7 (8%) | 11 (13%) | 3 (4%) |
| Allergic reactions and hypersensitivities | 1 (1%) | 4 (4%) | 3 (4%) | 3 (4%) |
| Potential anaphylaxis | 0 | 0 | 0 | 0 |
| Cerebrocardiovascular events | 0 | 0 | 0 | 1 (1%) |
| Malignancies | 0 | 0 | 0 | 0 |
| Inflammatory bowel disease | 0 | 0 | 1 (1%) | 0 |
| Depression | 0 | 1 (1%) | 0 | 0 |

Adalimumab represents an active reference arm; the study was not powered to test equivalence or noninferiority of active treatment arms to each other, including ixekizumab versus adalimumab. Q2W=every two weeks. Q4W=every four weeks. *Common treatment-emergent adverse events were defined as those that occurred at a frequency of at least 5% for patients receiving ixekizumab (both dosing regimens combined). †Neutropenia percentages are calculated for patients with a baseline and at least one post-baseline value. Placebo=86; adalimumab Q2W=89, ixekizumab Q2W=82, and ixekizumab Q4W=80.

***Table 3*: Adverse events during the 16-week masked treatment dosing period of COAST-V**

# Secukinumab and Ixekizumab

- Relevant efficacy on AS disease activity
- Inhibition of radiographic progression
- No TB reactivation risk
- Good safety profile

Seminars in Arthritis and Rheumatism ▮ (2015) ▮▮▮–▮▮▮
2015 Oct 22. pii: S0049-0172(15)00241-3.

Contents lists available at ScienceDirect

Seminars in Arthritis and Rheumatism

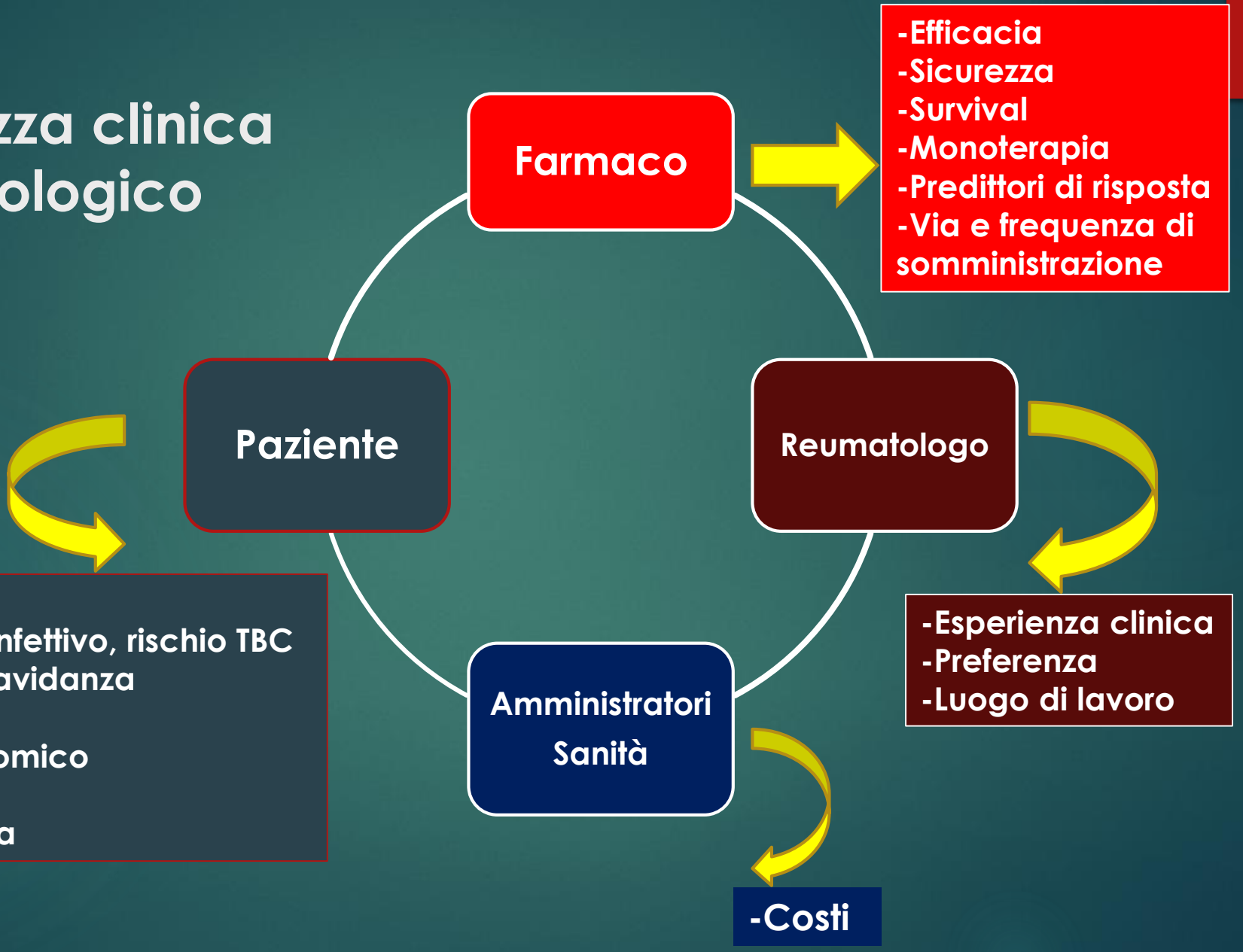
journal homepage: www.elsevier.com/locate/semarthrit

# Tailored first-line biologic therapy in patients with rheumatoid arthritis, spondyloarthritis, and psoriatic arthritis

Fabrizio Cantini[a,*], Laura Niccoli[a], Carlotta Nannini[a], Emanuele Cassarà[a], Olga Kaloudi[a], Ennio Giulio Favalli[b], Andrea Becciolini[b], Biggioggero Martina[b], Maurizio Benucci[c], Francesca Li Gobbi[c], Valentina Grossi[d], Maria Infantino[d], Francesca Meacci[d], Mariangela Manfredi[d], Serena Guiducci[e], Silvia Bellando-Randone[e], Marco Matucci-Cerinic[e], Rosario Foti[f], Marcella Di Gangi[f], Marta Mosca[g], Chiara Tani[g], Fabrizio Palmieri[h], Delia Goletti[i], On behalf of the Italian board for the TAilored BIOlogic therapy (ITABIO)[1]

[a] *Division of Rheumatology, Hospital of Prato, Piazza Ospedale, 1, 59100, Prato, Italy*
[b] *Department of Rheumatology, Gaetano Pini Institute, Milan, Italy*
[c] *Rheumatology Unit, Hospital S. Giovanni di Dio, Florence, Italy*
[d] *Immunology and Allergology Laboratory Unit, S. Giovanni di Dio Hospital, Florence*
[e] *Department of Biomedicine, Section of Rheumatology, University of Florence, Florence, Italy*
[f] *Rheumatology Unit, Vittorio-Emanuele University Hospital of Catania, Catania, Italy*
[g] *UO di Reumatologia, Dipartimento di Medicina Clinica e Sperimentale, Università di Pisa, Italy*
[h] *Clinical Department, "L. Spallanzani" National Institute for Infectious Diseases (INMI), IRCCS. Rome, Italy*
[i] *Translational Research Unit, Department of Epidemiology and Preclinical Research, "L. Spallanzani" National Institute for Infectious Diseases (INMI), IRCCS. Rome, Italy*

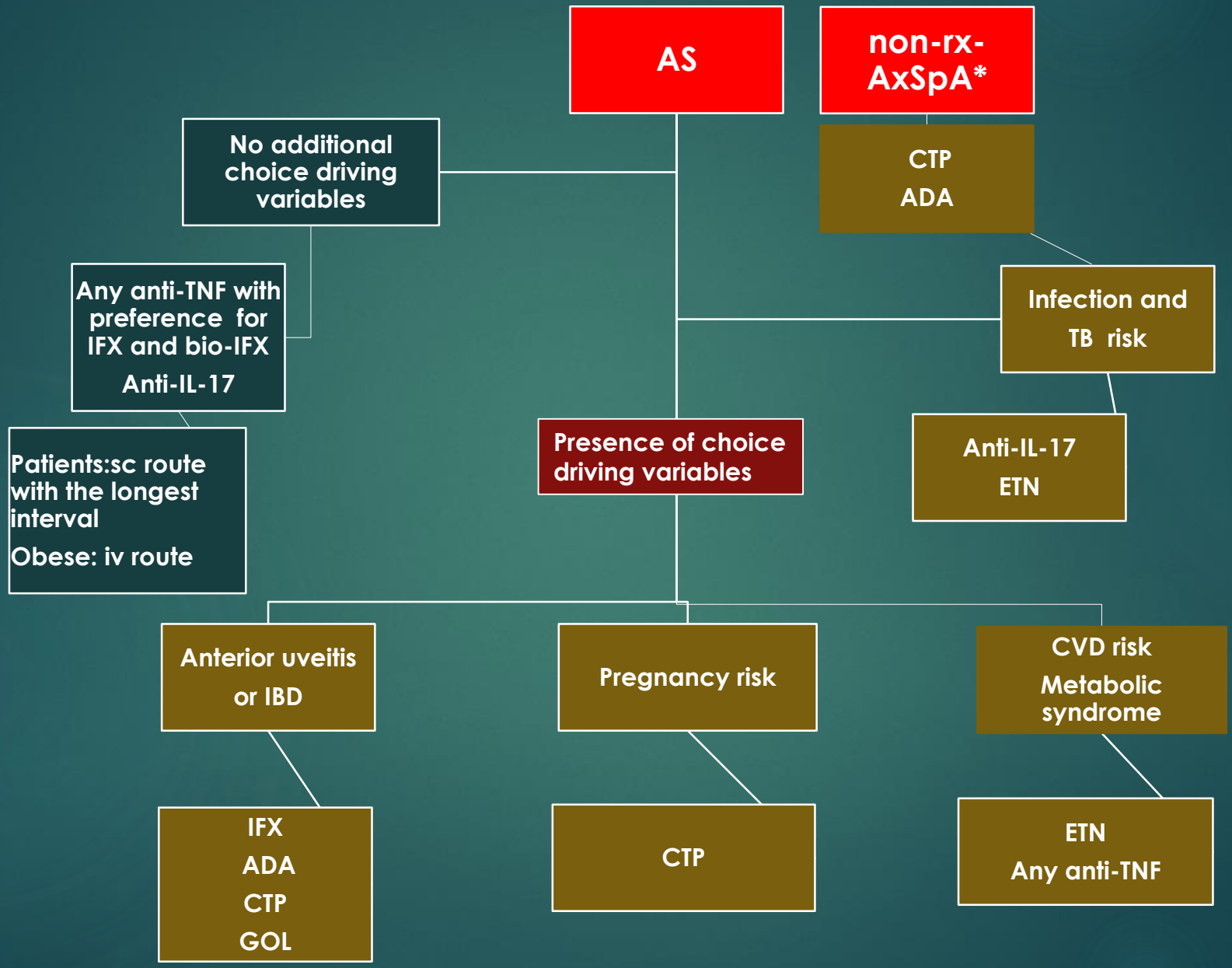
# Appropriatezza clinica
# Scelta del biologico



# Therapy choice in axial SpA
# Driving variables

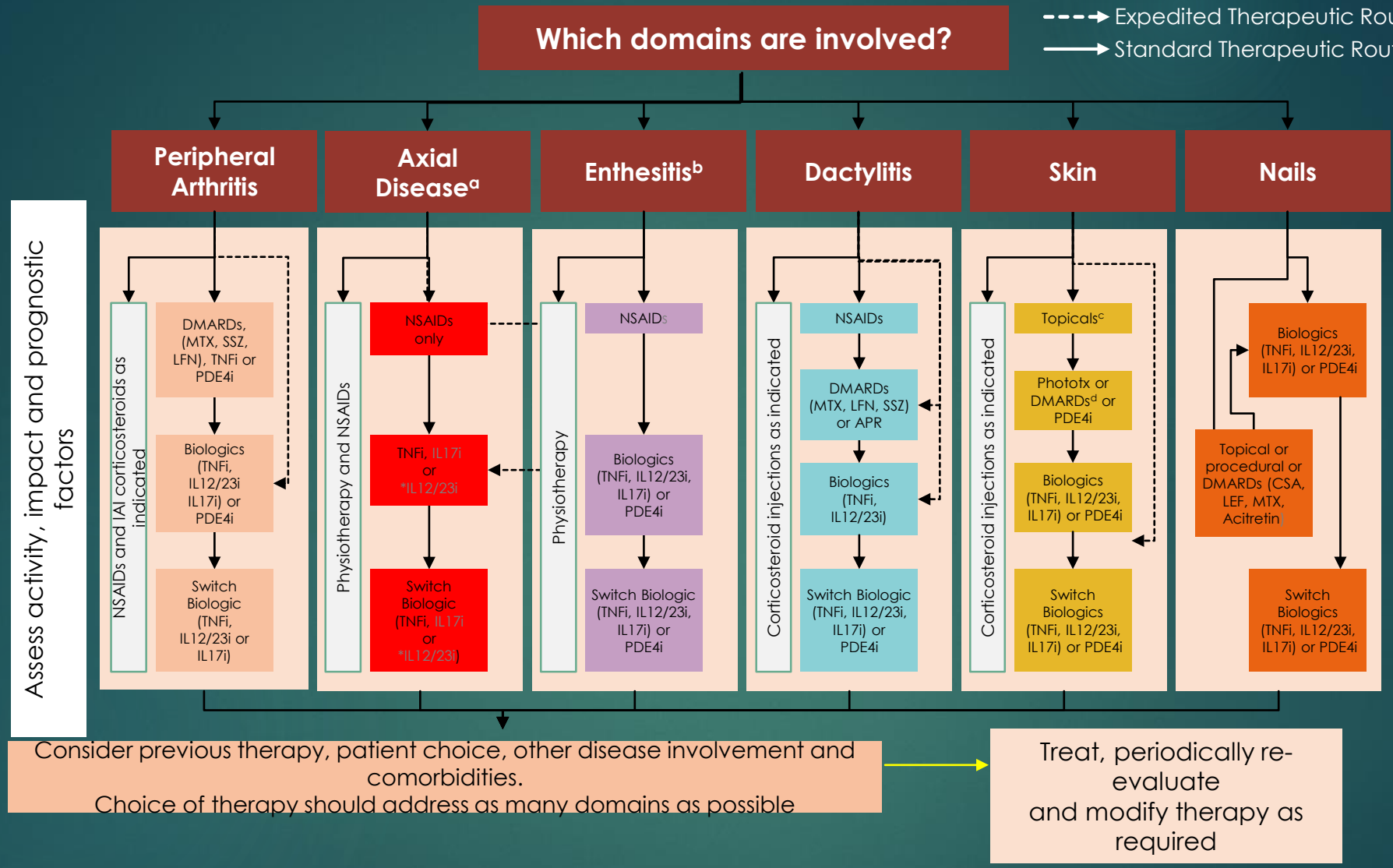
- Efficacy
- Safety
- Infection risk (including TB)
- Extra-articular manifestations
- Route of administration
- Cardiovascular risk
- Pregnancy risk
- Patient's preference
- Cost

## ITABIO recommendations for first biologic choice in AS and non-Rx axial SpA.




*Only ADA, CTP and ETN have been approved for non-rx-AxSpA in Europe.

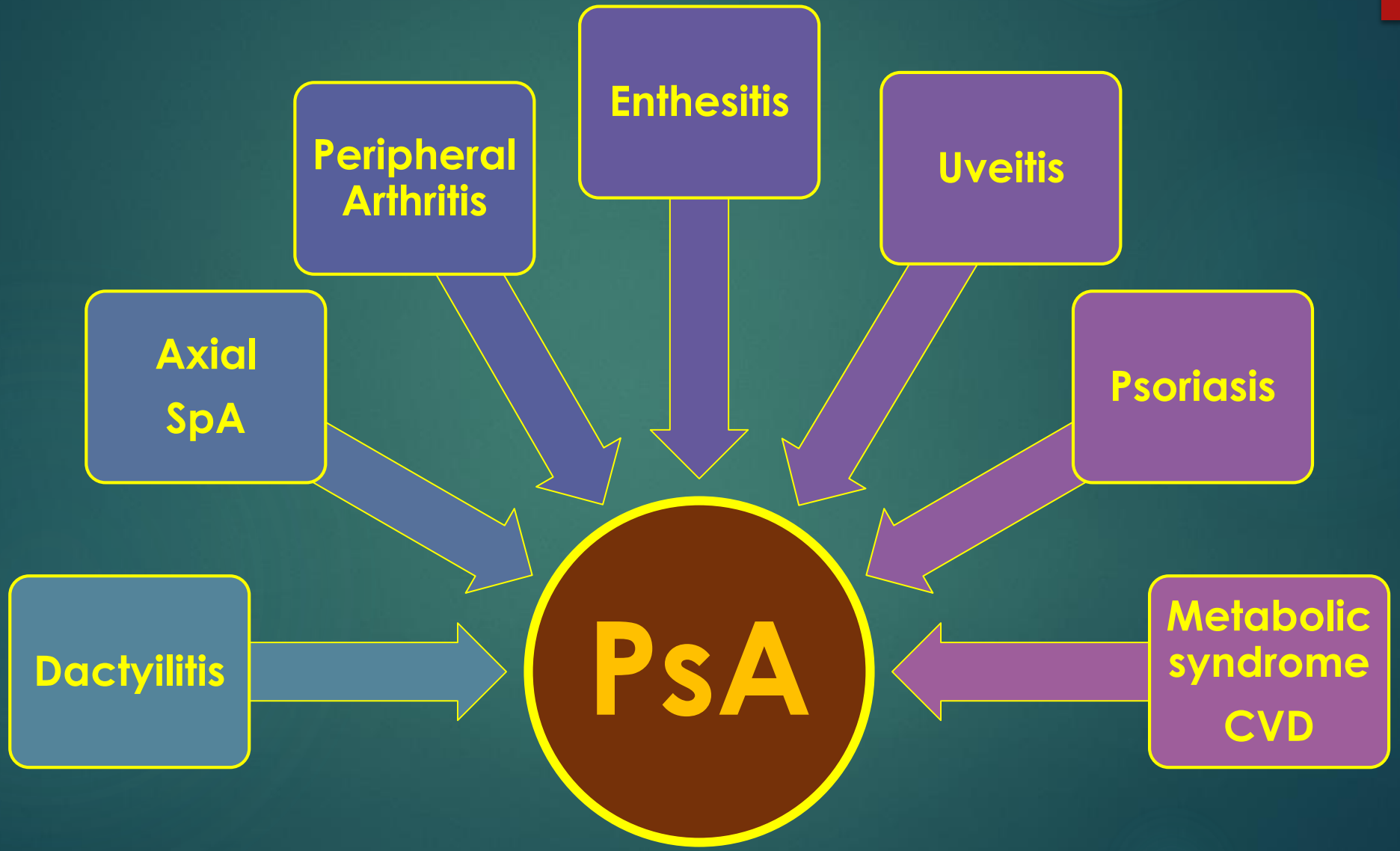
# PsA therapy



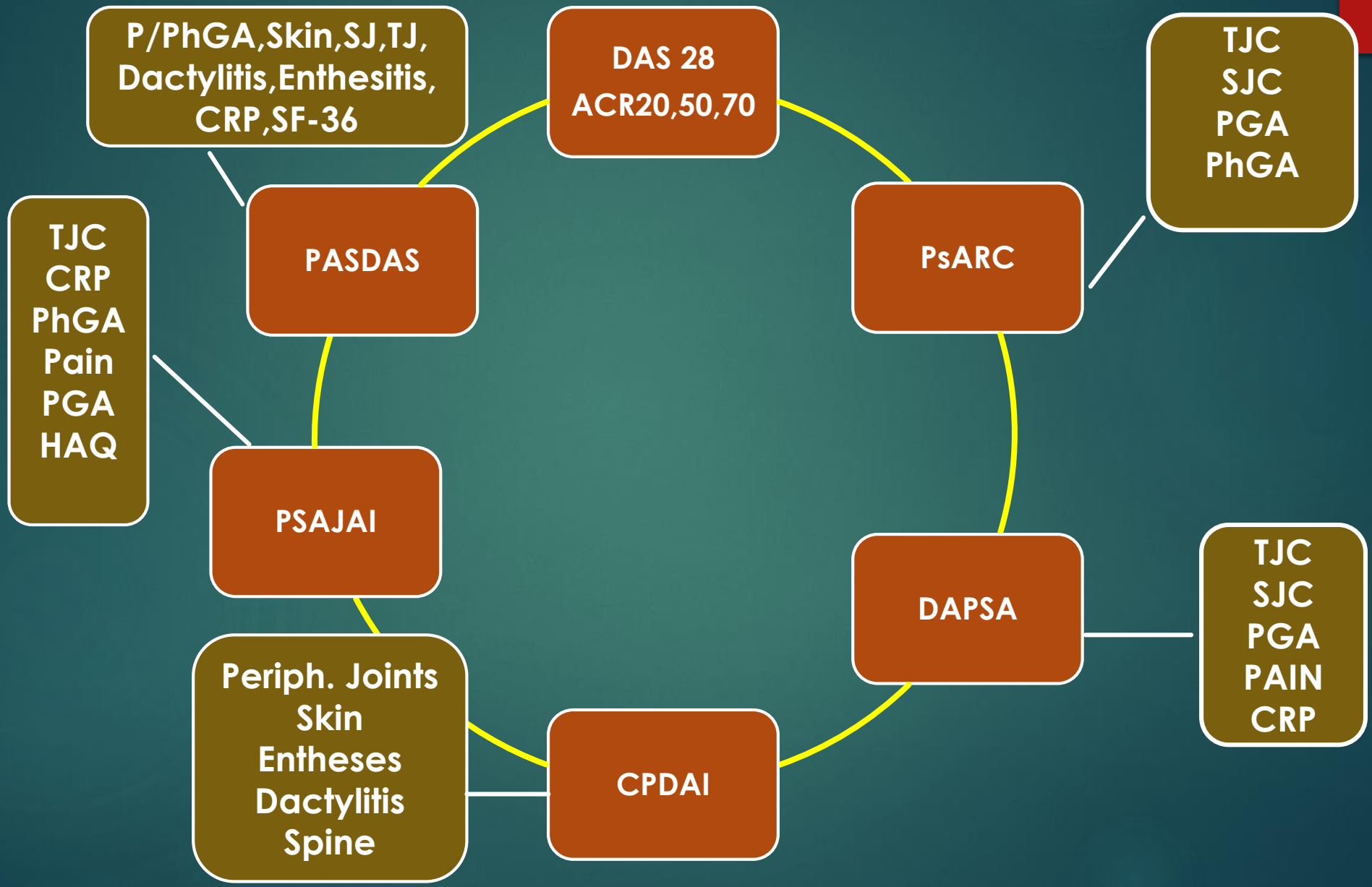

[a] No direct evidence for therapies in axial PsA, recommendations based on axial SpA literature; [b] Corticosteroid injections: consider on an individual basis due to potential for serious side effects; no clear evidence for efficacy; [c] Keratolytics, steroids, vitamin D analogues, emollients calcineurini; [d] MTX, CSA Acitretin, Fumaric acid esters. APR = apremilast; CSA = cyclosporin A; DMARD = disease-modifying anti-rheumatic drug; IAI = intra-articular injection; IL = interleukin; ILnni = ILnn inhibitor; LFN = leflunomide; MTX = methotrexate; NSAID = non-steroidal Anti-inflammatory drug;
PDE4 = phosphodiesterase 4; PDE4i = PDE4 inhibitor; SSZ = sulfasalazine; TNF = tumour necrosis factor; TNFi = TNF inhibitor;

Adapted from: 129. GRAPPA 2015, Annual Meeting of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis. Sweden, Stockholm

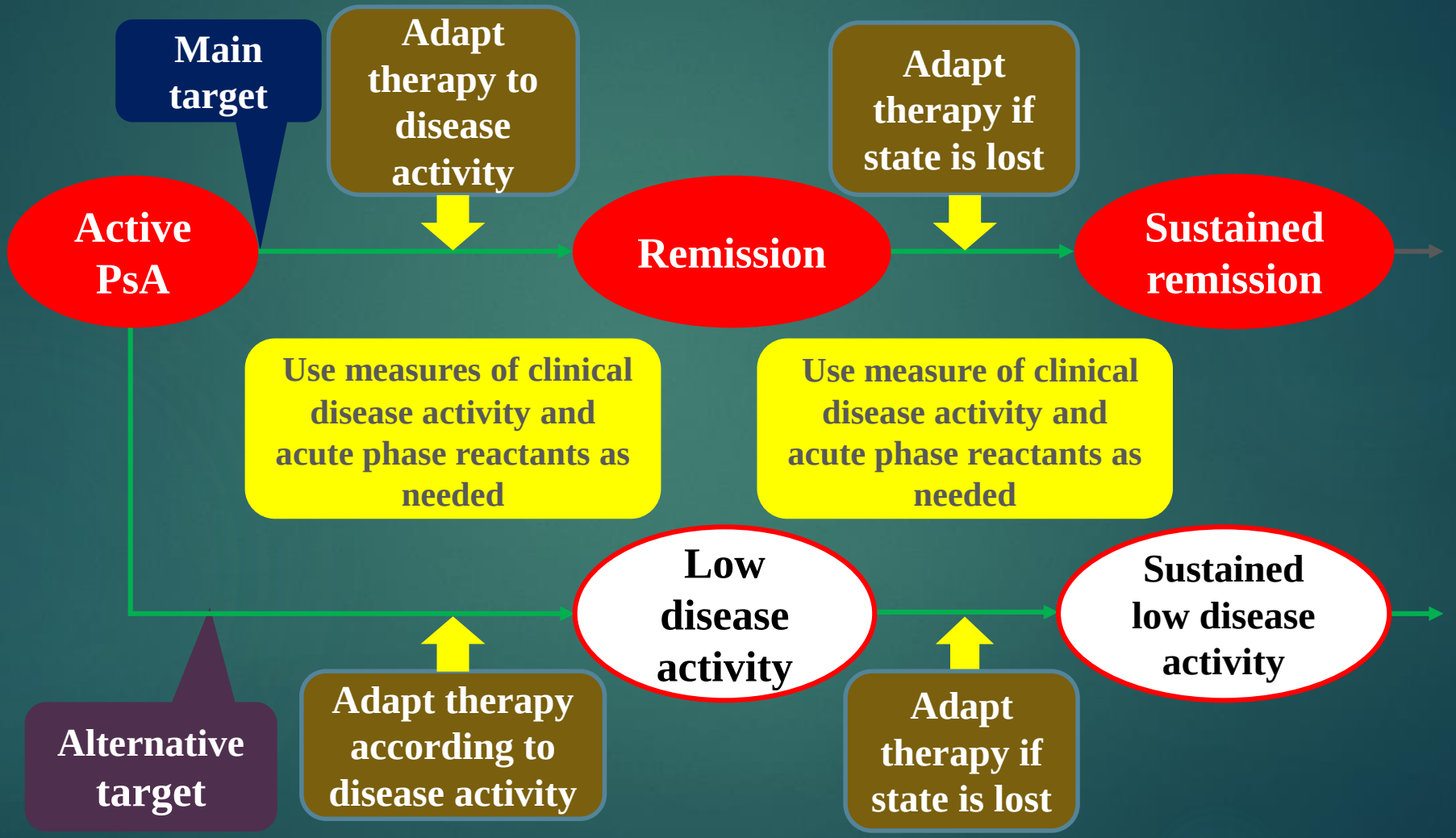
# PsA: clinical manifestations



# AP: misura dell'attività di malattia

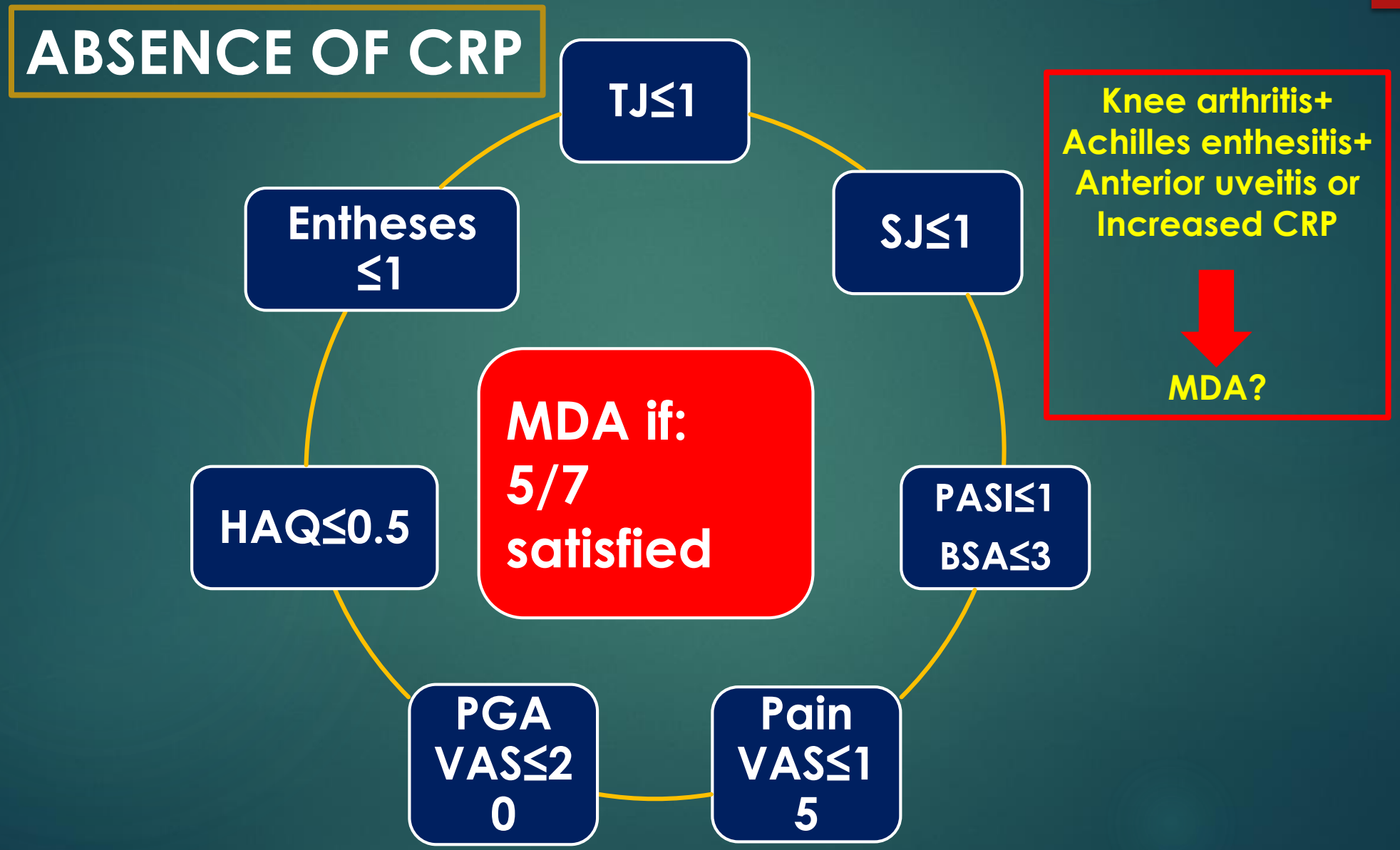


# PsA T2T strategy




Smolen JS, et al. Ann Rheum Dis 2014:73:6-16.

# PsA: MDA definition
# Coates LC, et al. Ann Rheum Dis 2010



# PsA: farmaco ideale

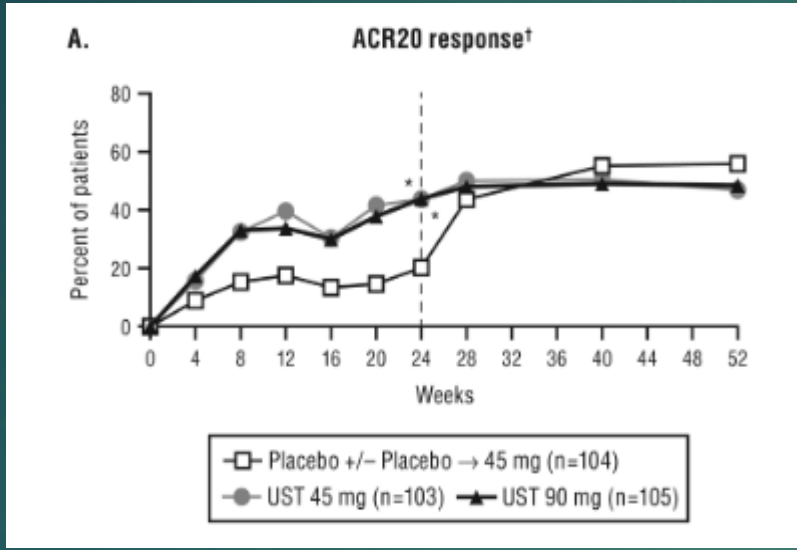
- Efficacia sulle manifestazioni articolari periferiche
- Efficacia sulle manifestazioni assiali
- Efficacia su entesite e dattilite
- Efficacia sulle manifestazioni extra-articolari
- Efficacia sulla psoriasi
- BMI
- Rallentamento/arresto della progressione radiologica
- Persistenza di efficacia nel tempo
- Buon profilo di sicurezza d'impiego
- Via ed intervalli di somministrazione preferita dal paziente
- Basso costo

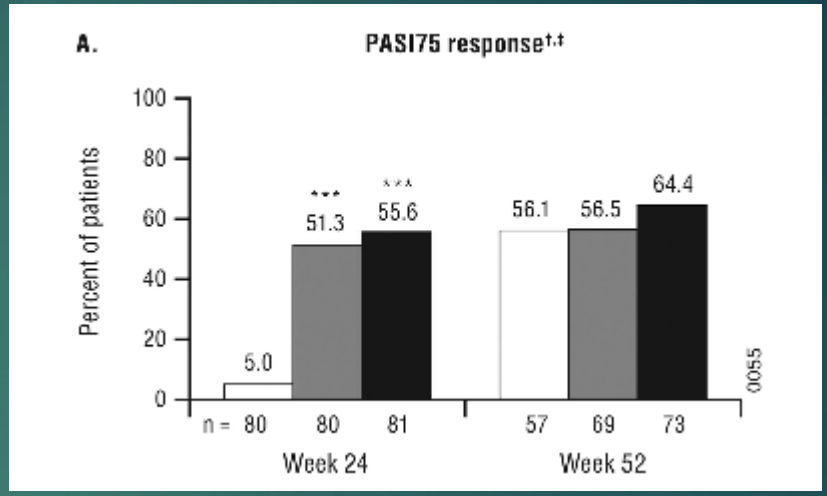
# Anti-TNFs in PsA

- Efficacia nel 60-70% dei pazienti
- Evidenza sulla capacità di rallentare/arrestare la progressione radiologica
- Anti-TNFs monoclonali efficaci sull'Uveite
- Efficacia sulla psoriasi
- Evidenza di efficacia sulle manifestazioni cardiovascolari
- Efficacia sulla IBD che si associa nel 7%-8% dei casi
- Rischio infettivo aumentato
- Rischio di riattivazione di TBC latente aumentato

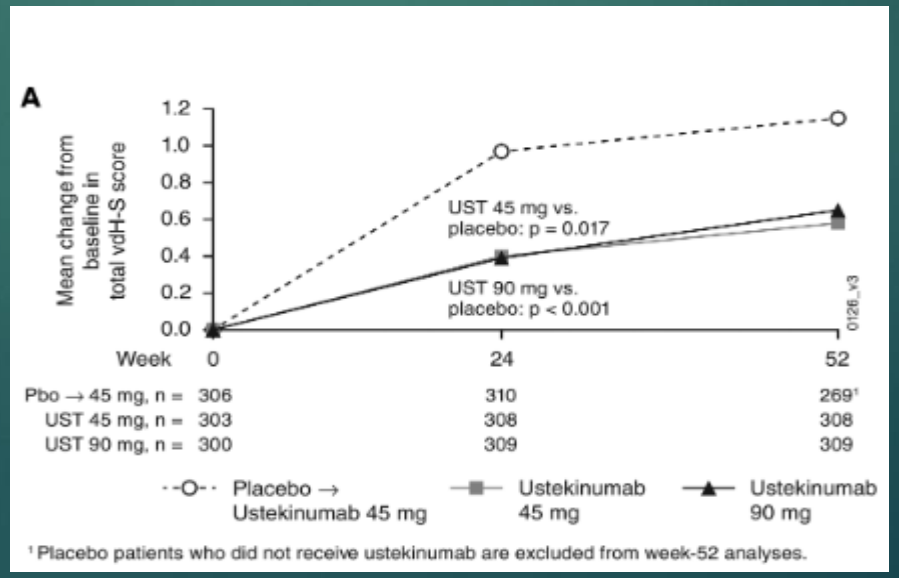
# Ustekinumab in AP

## Ritchlin C, et al. Ann Rheum Dis 2013




Radiographic outcome




Efficacia sulla M. Di Crohn

# Secukinumab Inhibition of Interleukin-17A in Patients with Psoriatic Arthritis

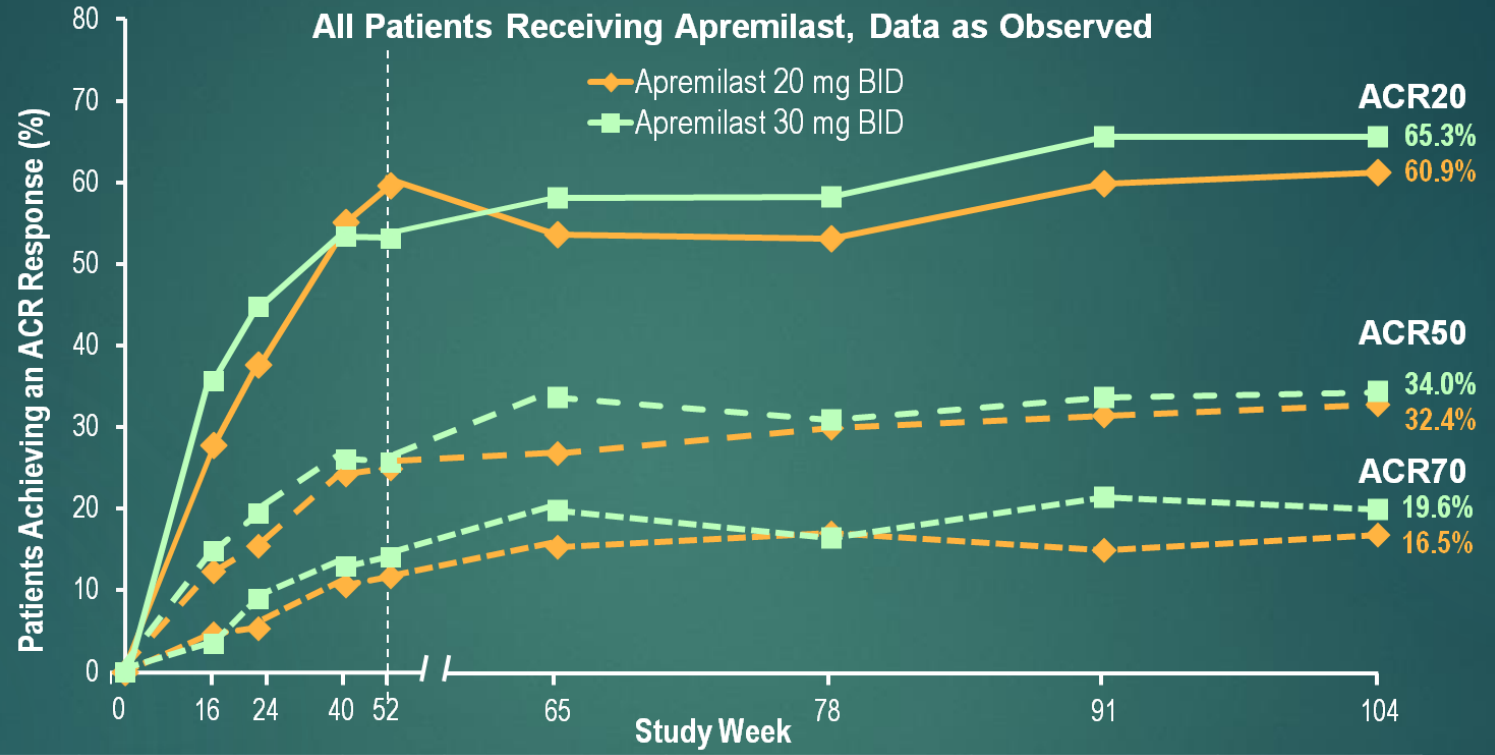
**Mease PJ, et la. NEJM 2015**

**Table 2. Comparison of Efficacy at Week 24 during the Placebo-Controlled Phase.***

| Outcome | Secukinumab, 150 mg (N=202) | Secukinumab, 75 mg (N=202) | Placebo (N=202) |
|---|---|---|---|
| ACR20 response: primary end point — no. (%)† | 101 (50.0)‡ | 102 (50.5)‡ | 35 (17.3) |
| Prespecified secondary end points | | | |
| PASI 75 response — no./total no. (%)§ | 66/108 (61.1)‡ | 70/108 (64.8)‡ | 9/109 (8.3) |
| PASI 90 response — no./total no. (%)§ | 49/108 (45.4)‡ | 53/108 (49.1)‡ | 4/109 (3.7) |
| Change from baseline in DAS28-CRP | −1.62±0.08‡ | −1.67±0.09‡ | −0.77±0.12 |
| Change from baseline in SF-36 physical component summary | 5.91±0.53‡ | 5.41±0.52‡ | 1.82±0.72 |
| Change from baseline in disability assessment (HAQ-DI score) | −0.40±0.04‡ | −0.41±0.04‡ | −0.17±0.05 |
| ACR50 response — no. (%) | 70 (34.7)‡ | 62 (30.7)‡ | 15 (7.4) |
| Change from baseline in joint structural damage (mTSS score)¶ | 0.13±0.09‖ | 0.02±0.12‖ | 0.57±0.19 |
| Patients with resolution of dactylitis — no./total no. (%)** | 109/208 (52.4)‖ | | 18/116 (15.5) |
| Patients with resolution of enthesitis — no./total no. (%)** | 121/255 (47.5)‖ | | 15/117 (12.8) |

PALACE 1

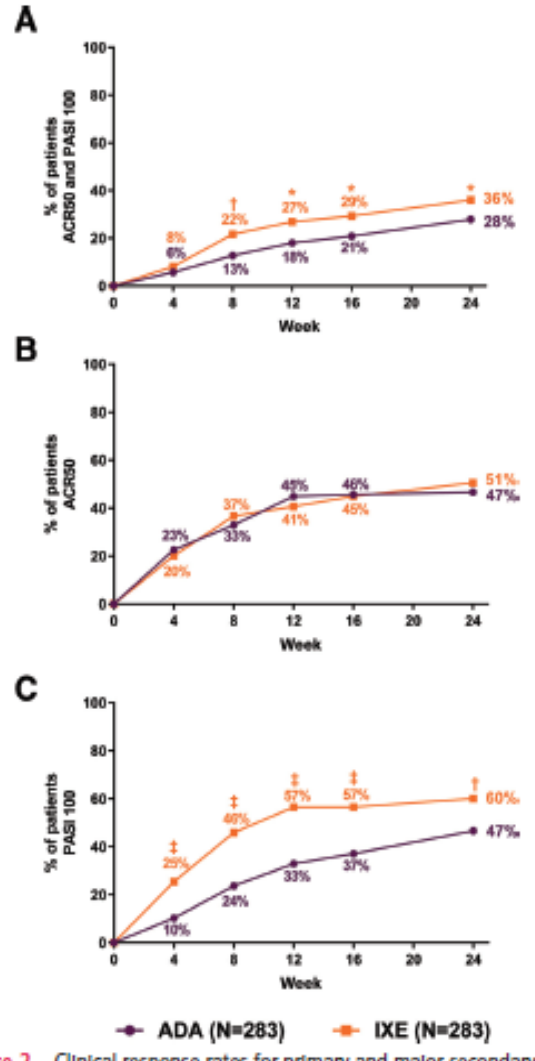
# Apremilast: Modified ACR20/50/70 Responses Over 104 Weeks




| | | | | | | |
|---|---|---|---|---|---|---|
| ACR20 | Apremilast 20 mg BID, n/m | 109/183 | 89/167 | 85/161 | 88/148 | 84/138 |
| | Apremilast 30 mg BID, n/m | 101/190 | 96/166 | 92/159 | 98/150 | 94/144 |
| ACR50 | Apremilast 20 mg BID, n/m | 45/180 | 44/166 | 47/159 | 47/151 | 45/139 |
| | Apremilast 30 mg BID, n/m | 49/191 | 56/168 | 49/160 | 50/150 | 49/144 |
| ACR70 | Apremilast 20 mg BID, n/m | 21/179 | 25/168 | 26/156 | 22/151 | 23/139 |
| | Apremilast 30 mg BID, n/m | 27/191 | 33/169 | 26/161 | 32/152 | 28/143 |

Analyses include all patient data, including the placebo-controlled period, regardless of when patients started taking apremilast (baseline, Week 16, or Week 24).
ACR20/50/70=American College of Rheumatology 20/50/70; n/m=number of responders/number of patients with sufficient data for evaluation.
Kavanaugh A, et al. ACR 2014 [poster 1590].

# Ixekizumab in PsA



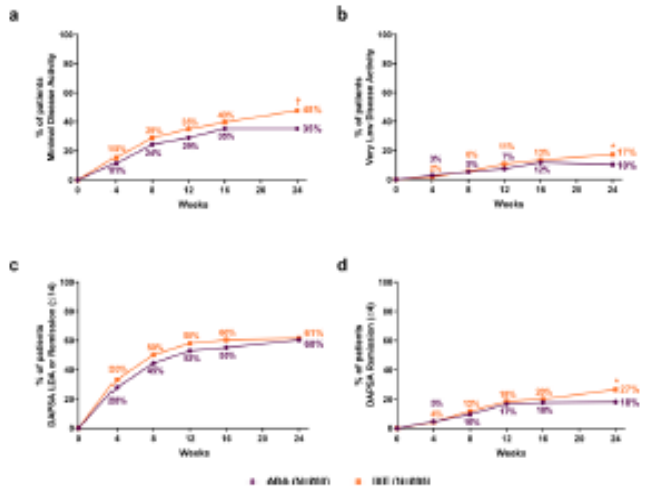




**Figure 3** Clinical response rates for treat-to-target outcomes through week 24. (A) Percentage of patients achieving minimal disease activity. (B) Percentage of patients achieving very low disease activity. (C) Percentage of patients achieving a DAPSA score of ≤14 (LDA or remission). (D) Percentage of patients achieving a DAPSA score ≤4 (remission). IXE versus ADA: *P<0.05, †p<0.01, ‡p<0.001. ADA, adalimumab; DAPSA, Disease Activity in Psoriatic Arthritis; IXE, Ixekizumab; LDA, low disease activity.

Digestif (EPIMAD) criteria for adjudication of suspected IBD, where 'probable' and 'definite' classifications are considered as confirmed cases.[14] Three TEAEs were identified in two IXE-treated patients as suspected IBD. One IXE-treated patient had an event reported as 'colitis' that was sent for adjudication, but there was insufficient information to make a definitive classification. The same patient also had an event of 'colitis ulcerative', adjudicated as possible ulcerative colitis, which resulted in study discontinuation. Another IXE-treated patient with no prior medical history of IBD had an event reported as 'colitis' that was adjudicated as probable

**Table 3** Safety outcomes

| | IXE (n=283) | ADA (n=283) |
|---|---|---|
| Extent of exposure, mean days (total patient-years) | 236.8 (183.5) | 228.9 (117.3) |
| Treatment-emergent adverse events | 197 (69.6) | 173 (61.1) |
| Mild | 97 (34.3) | 87 (30.7) |
| Moderate | 91 (32.2) | 71 (25.1) |
| Severe | 9 (3.2) | 15 (5.3) |
| Serious adverse events | 10 (3.5) | 24 (8.5) |
| Deaths | 0 | 0 |
| Discontinuations due to adverse events | 7 (2.5) | 13 (4.6) |
| Adverse events of special interest | | |
| Infections | 102 (36.0) | 87 (30.7) |
| Serious infections | 4 (1.4) | 8 (2.8) |
| *Candida* infections | 7 (2.5) | 2 (0.7) |
| Injection-site reactions | 27 (9.5) | 9 (3.2) |
| Allergic/hypersensitivity reactions | 7 (2.5) | 11 (3.9) |
| Potential anaphylaxis | 0 | 0 |
| Cytopaenias | 5 (1.8) | 11 (3.9) |
| Cerebrocardiovascular events* | 3 (1.1) | 5 (1.8) |
| Malignancies | 0 | 3 (1.1) |
| Depression | 3 (1.1) | 7 (2.5) |
| Inflammatory bowel disease | 2 (0.7)† | 0 |
| Ulcerative colitis | 1 (0.4)‡ | 0 |
| Crohn's disease | 1 (0.4)§ | 0 |

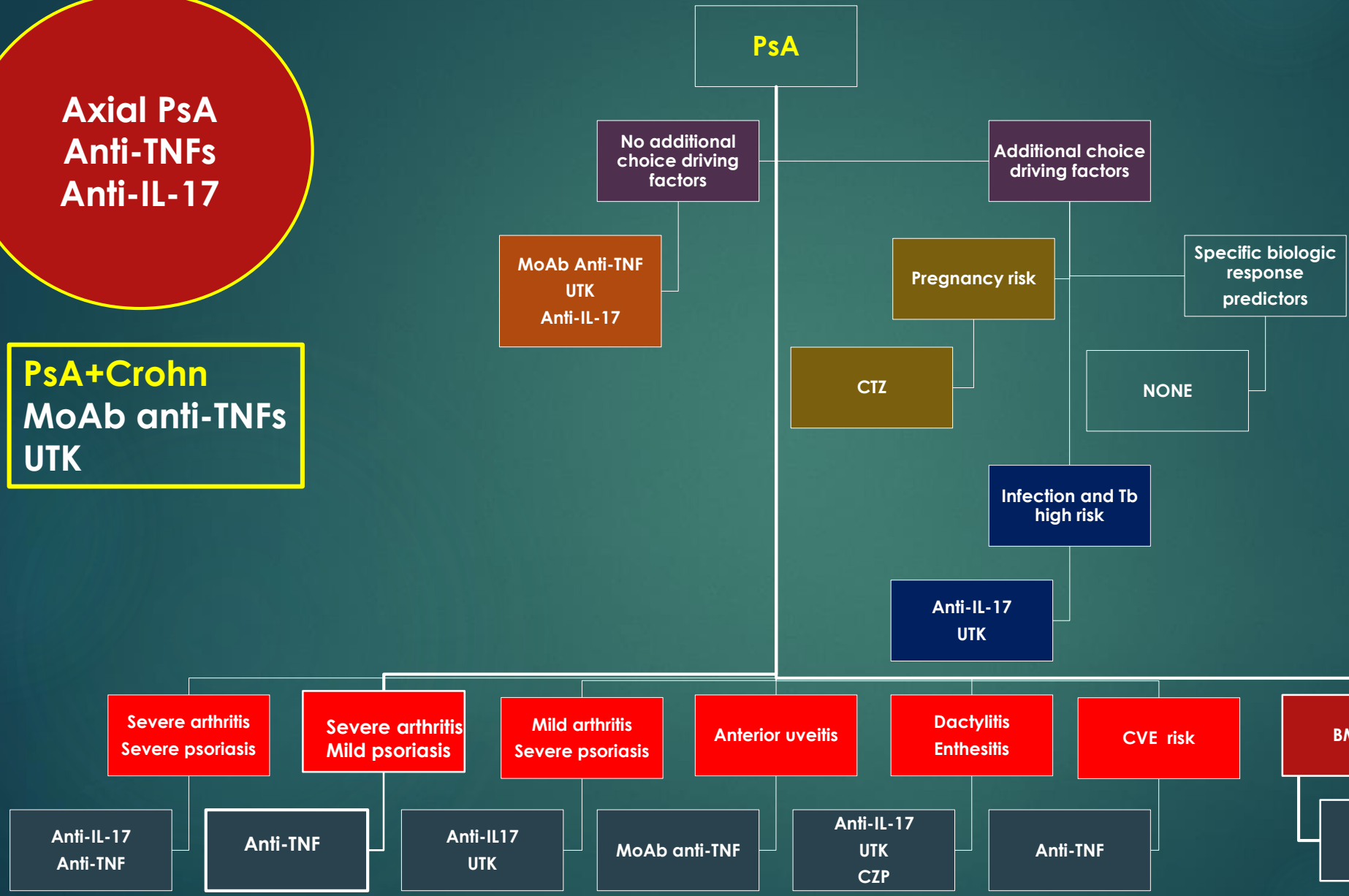
# Non-anti-TNFs in PsA

- Efficacia sulle manifestazioni articolari degli anti-IL-17, lievemente inferiore per Apremilast
- Efficacia su dattilite ed entesite superiore a quella degli anti-TNFs
- Efficacia sulla psoriasi superiore a quella degli anti-TNFs
- Rischio infettivo assente per Apremilast
- Buon profilo di sicurezza d'impiego
- Rischio di riattivazione TBC assente

# ITABIO recommendations for first biologic choice in patients with PsA

**Axial PsA**
**Anti-TNFs**
**Anti-IL-17**

**PsA+Crohn**
**MoAb anti-TNFs**
**UTK**




**Small molecule**
**Apremilast**
**-Elevato rischio Infettivo**
**-Rischio TB**
**-Pregresse neoplasie**

# Grazie per l'attenzione