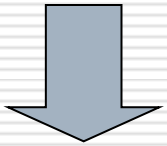
Εισαγωγή νέων αντι-TNF παραγόντων
Από τη βελτίωση της νόσου στη βελτίωση της ποιότητας ζωής:
Το παράδειγμα του Golimumab

Σπύρος Ν Νίκας
Ρευματολόγος
Ιωάννινα

3ο Επιστημονικό Καλοκαιρινό Διαδραστικό Διεταιρικό Συμπόσιο
NAVARINO DUNES
23 – 26 Ιουνίου 2011

Βιολογικοί παράγοντες & RA

Η βελτίωση της νόσου (DAS 28, ACR, CRP)



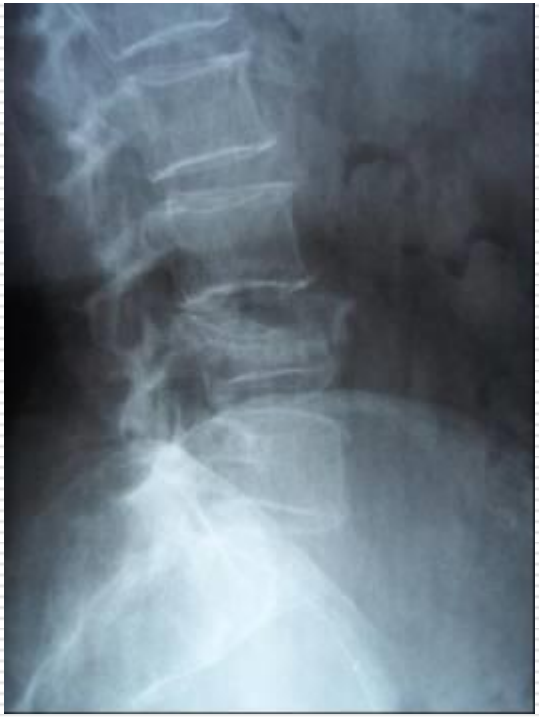
Βελτίωση της ποιότητας ζωής ???

Είναι αυτονόητο ???
Είναι δεδομένο ???

Παράδειγμα Νο 1

- Όλα (???) τα διφωσφωνικά έχουν ένδειξη για προστασία κατάγματος ισχίου

Παράδειγμα No2



Παράδειγμα No2

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 6, 2009 VOL. 361 NO. 6

A Randomized Trial of Vertebroplasty for Painful Osteoporotic Vertebral Fractures

Rachelle Buchbinder, Ph.D., Richard H. Osborne, Ph.D., Peter R. Ebeling, M.D., John D. Wark, Ph
Peter Mitchell, M.Med., Chris Wriedt, M.B., B.S., Stephen Graves, D. Phil., Margaret P. Staples, Ph
and Bridie Murphy, B.Sc.

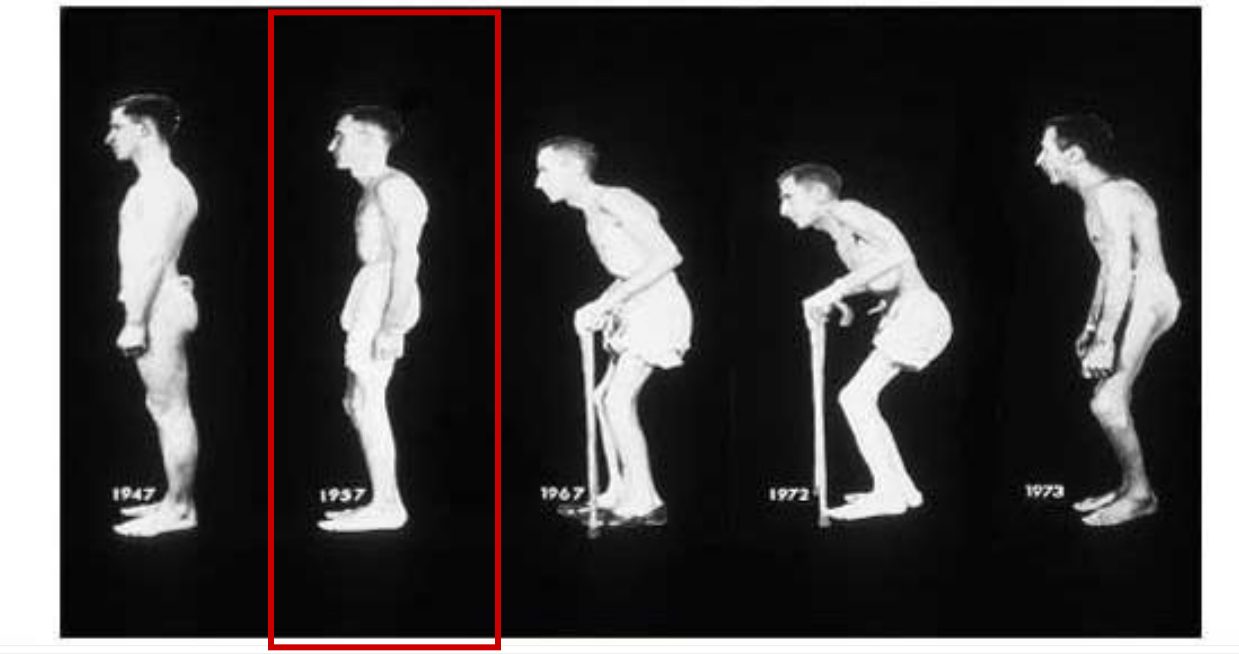
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures

David F. Kallmes, M.D., Bryan A. Comstock, M.S., Patrick J. Heagerty, Ph.D., Judith A. Turner, Ph.D., David J. Wilson, F.R.C.R., Terry H. Diamond, F.R.A.C.P., Richard Edwards, F.R.C.R., Leigh A. Gray, M.S., Lydia Stout, B.S., Sara Owen, M.Sc., William Hollingworth, Ph.D., Basavaraj Ghdoke, M.D., Deborah J. Annesley-Williams, F.R.C.R., Stuart H. Ralston, F.R.C.P., and Jeffrey G. Jarvik, M.D., M.P.H.

Παράδειγμα Νο3



Βιολογικοί παράγοντες / ποιότητα ζωής

- Δεν είναι πάντα όλα δεδομένα
- Δεν υπάρχει πάντα άμεση συσχέτιση
  - Δεικτών φλεγμονής
  - Ποιότητα ζωής

PA

Πολλές μελέτες δείχνουν σημαντική έκπτωση της ποιότητας ζωής ασθενών με PA

- Σωματική λειτουργία
- Ψυχολογική κατάσταση
- Κοινωνική λειτουργία

Strand V, Khanna D The impact of rheumatoid arthritis and treatment on patients' lives. Clin Exp Rheumatol.2010 May-Jun;28(3 Suppl 59):S32-40. Epub 2010 Jun 22.

Οι θεραπευτικοί στόχοι γιατρού και ασθενούς δεν είναι απαραίτητα ίδιοι

Για το γιατρό

- Μείωση του πόνου
- Επίτευξη ύφεσης ή χαμηλής ενεργότητας νόσου
- Αναστολή της ακτινολογικής εξέλιξης
- Βελτίωση της σωματικής λειτουργίας

Van der Heijde D. Ann Rheum Dis 2001;60:iii47-iii50.

Για τον ασθενή

- Μείωση της επίδρασης της νόσου στην καθημερινή ζωή
- Μειωμένη και αραιή λήψη φαρμάκων
- Ασφαλή φάρμακα
- Επικοινωνία με το γιατρό

McInnes B, et al. Ann Rheum Dis 2009;68(suppl 3):240.

Τι επιθυμούν οι ασθενείς με ΡΑ;

51% πιστεύουν ότι η ΡΑ ελέγχει τη ζωή τους

33% επιθυμούν πιο αποτελεσματικές θεραπείες

25% ασθενών σε βιολογική θεραπεία συνεχίζουν να έχουν υψηλά επίπεδα πόνου

56% επιθυμούν λιγότερο πόνο ή καύσο κατά την ένεση

88% προτιμούν μηνιαίο δοσολογικό σχήμα

48% χρειάζονται βοήθεια στην καθημερινότητά τους

McInnes IB, et al. EULAR 2010. Abstract AB0302-HP.

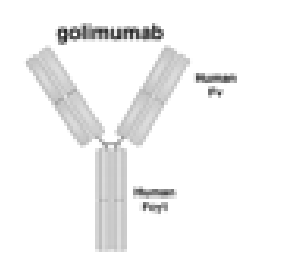
McInnes IB, et al. Ann Rheum Dis. 2009;68(suppl 3):240.

Golimumab

- CNTO -148
- Simponi ™
- Πλήρως ανθρώπινο anti TNF –α μονοκλωνικό αντίσωμα
- Θεραπεία PA , AS , PsA (ενεργό) (FDA : 24/4/09)

Golimumab

- 50 mg / 100 mg (> 100 kg) (1 φορά το μήνα)
- Χορηγείται SC / IV
- Με / χωρίς MTX (ΨΑ , ΑΣ)



Golimumab

- Δημιουργήθηκε μετά από ανοσοποίηση γενετικά ειδικού ποντικιού με ανθρώπινο TNF
  - Παράγει ΜΟΝΟ ανθρώπινες ανοσοσφαιρίνες
- Αντίσωμα με ανθρώπινες μεταβλητές & σταθερές περιοχές
- Δεσμεύεται και με τον διαλυτό και με τον διαμεμβρανικό TNF

Golimumab

1η κλινική μελέτη (phase I)

Pharmacokinetics and Safety of Golimumab, a Fully Human Anti-TNF-α Monoclonal Antibody, in Subjects With Rheumatoid Arthritis

Honghui Zhou, PhD, FCP, Haishan Jang, PhD, Roy M. Fleischmann, MD, Esther Bouman-Thio, MD, Zhenhua Xu, PhD, FCP, Joseph C. Marini, PhD, Charles Pendley, PhD, Qun Jiao, MS, Gopi Shankar, PhD, Stanley J. Marciniak, MBA, Stanley B. Cohen, MD, Mahboob U. Rahman, MD, PhD, Daniel Baker, MD, Mary Ann Mascelli, PhD, Hugh M. Davis, PhD, and Daniel E. Everitt, MD

Journal of Clinical Pharmacology, 2007;47:383-396
©2007 the American College of Clinical Pharmacology

Golimumab
κλινική μελέτη σε PA (phase II)

ARTHRITIS & RHEUMATISM
Vol. 58, No. 4, April 2008, pp 964–975
DOI 10.1002/art.23383
© 2008, American College of Rheumatology

Golimumab in Patients With Active Rheumatoid Arthritis Despite Treatment With Methotrexate

A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study

Jonathan Kay,[1] Eric L. Matteson,[2] Bhaskar Dasgupta,[3] Peter Nash,[4] Patrick Durez,[5] Stephen Hall,[6] Elizabeth C. Hsia,[7] John Han,[8] Carrie Wagner,[8] Zhenhua Xu,[8] Sudha Visvanathan,[8] and Mahboob U. Rahman[7]

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		Golimumab + MTX				
	Placebo + MTX (n = 35)	50 mg every 4 weeks (n = 35)	50 mg every 2 weeks (n = 34)	100 mg every 4 weeks (n = 34)	100 mg every 2 weeks (n = 34)	Combined (n = 137)
ACR20, no. (%) [*P*]	13 (37.1)	21 (60.0) [0.056]	17 (50.0) [0.281]	19 (55.9) [0.119]	27 (79.4) [<0.001]	84 (61.3) [0.010]
ACR50, no. (%) [*P*]	2 (5.7)	13 (37.1) [0.001]	8 (23.5) [0.036]	10 (29.4) [0.009]	11 (32.4) [0.005]	42 (30.7) [0.003]
ACR70, no. (%) [*P*]	0 (0.0)	3 (8.6) [0.077]	5 (14.7) [0.018]	6 (17.6) [0.009]	3 (8.8) [0.072]	17 (12.4) [0.028]
ACR-N						
Mean ± SD	−2.4 ± 50.0	22.7 ± 46.8	16.2 ± 57.4	24.8 ± 41.7	30.4 ± 42.3	23.5 ± 47.2
Median (IQR) [*P*]	0.0 (−12.5, 28.6)	37.4 (0.0, 54.4) [0.006]	19.4 (−1.0, 49.0) [0.095]	22.3 (0.0, 55.6) [0.010]	35.6 (20.0, 56.6) [<0.001]	33.3 (0.0, 54.4) [0.001]
DAS28 using CRP level						
Mean ± SD change from baseline	−0.9 ± 1.0	−1.9 ± 1.3	−1.4 ± 1.3	−1.9 ± 1.5	−1.9 ± 1.1	−1.8 ± 1.3
Median (IQR) change from baseline [*P*]	−1.0 (−1.8, −0.2)	−1.8 (−2.5, −1.3) [0.004]	−1.3 (−1.9, −0.6) [0.162]	−2.2 (−3.2, −0.9) [0.006]	−1.8 (−2.5, −1.1) [0.002]	−1.7 (−2.5, −1.0) [0.002]
Good response, no. (%)	7 (20.0)	13 (37.1)	10 (29.4)	12 (35.3)	17 (50.0)	52 (38.0)
Moderate response, no. (%)	12 (34.3)	13 (37.1)	13 (38.2)	11 (32.4)	12 (35.3)	49 (35.7)
No response, no. (%)	16 (45.7)	9 (25.7)	11 (32.4)	11 (32.4)	5 (14.7)	36 (26.8)
P†		0.081	0.256	0.256	0.005	0.025
Remission, no. (%) [*P*]‡	2 (5.7)	7 (20.0) [0.074]	9 (26.5) [0.019]	11 (32.4) [0.005]	9 (26.5) [0.019]	36 (26.3) [0.009]
DAS28 using ESR						
Mean ± SD change from baseline	−1.0 ± 1.1	−2.1 ± 1.4	−1.9 ± 1.5	−2.1 ± 1.7	−2.3 ± 1.2	−2.1 ± 1.4
Median (IQR) change from baseline [*P*]	−1.0 (−2.0, 0.0)	−2.2 (−2.8, −1.5) [0.003]	−1.6 (−2.6, −1.0) [0.059]	−2.7 (−3.6, −0.9) [0.015]	−2.2 (−2.9, −1.5) [<0.001]	−2.1 (−3.0, −1.2) [<0.001]
Good response, no. (%)	2 (5.7)	3 (8.6)	5 (14.7)	9 (26.5)	8 (23.5)	25 (18.2)
Moderate response, no. (%)	13 (37.1)	22 (62.9)	17 (50.0)	13 (38.2)	21 (61.8)	73 (53.3)
No response, no. (%)	20 (57.1)	10 (28.6)	12 (35.3)	12 (35.3)	5 (14.7)	39 (28.5)
P†		0.016	0.069	0.069	<0.001	0.001
Remission, no. (%) [*P*]‡	0 (0)	2 (5.7) [0.151]	4 (11.8) [0.037]	3 (8.8) [0.072]	4 (11.8) [0.037]	13 (9.5) [0.058]

Golimumab

κλινική μελέτη σε PA (phase II):

ARTHRITIS & RHEUMATISM
Vol. 58, No. 4, April 2008, pp 964–975
DOI 10.1002/art.23383
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Golimumab in Patients With Active Rheumatoid Arthritis Despite Treatment With Methotrexate

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Jonathan Kay,[1] Eric L. Matteson,[2] Bhaskar Dasgupta,[3] Peter Nash,[4] Patrick Durez,[5] Stephen Hall,[6] Elizabeth C. Hsia,[7] John Han,[8] Carrie Wagner,[8] Zhenhua Xu,[8] Sudha Visvanathan,[8] and Mahboob U. Rahman[7]

Αρχική εξέταση:

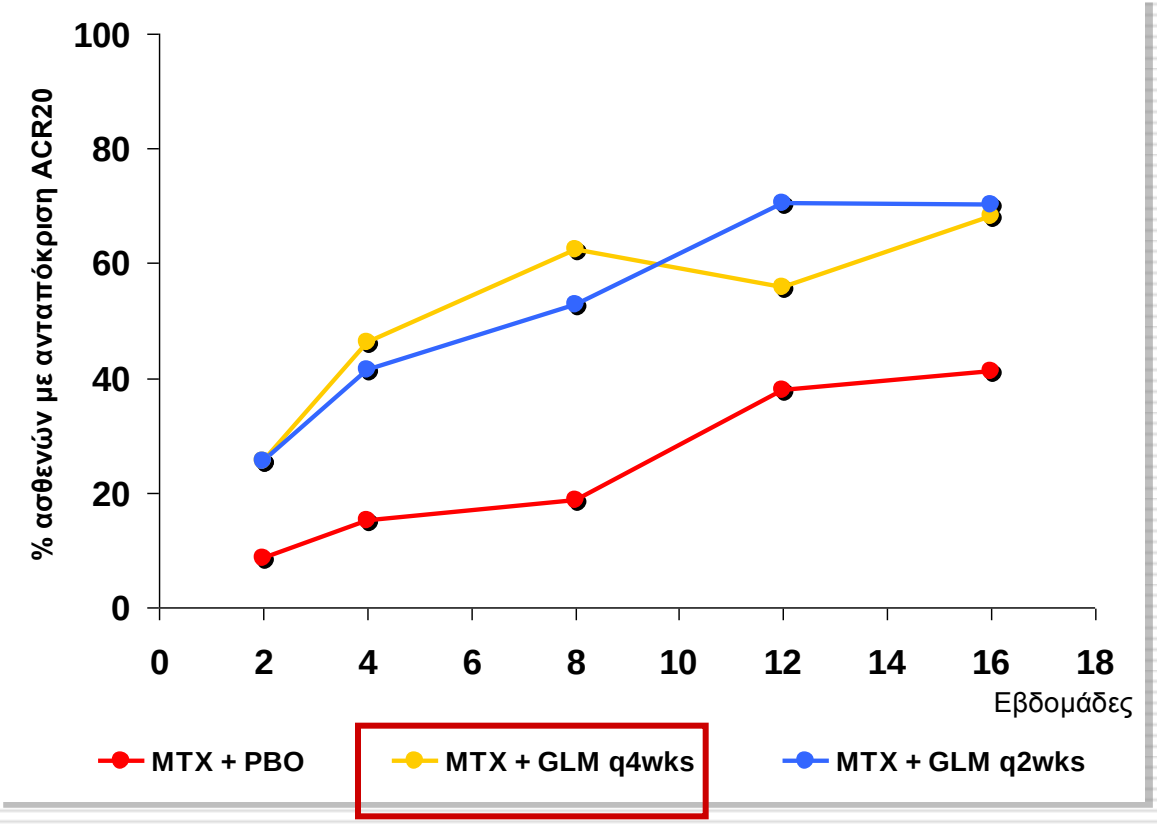
Μέση διάρκεια νόσου: 5,6-9 έτη

Μέση CRP (mg/dl): 1,4-2,1

Μέσο DAS28 (CRP): 4,8-5,4

Μέσο HAQ: 1,3-1,8

ACR20 με δόση 50 mg κάθε 2 ή 4 εβδομάδες



ARTHRITIS & RHEUMATISM
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Table 1. Baseline characteristics of the patients*

		Golimumab + MTX					
	Placebo + MTX (n = 35)	50 mg every 4 weeks (n = 35)	50 mg every 2 weeks (n = 34)	100 mg every 4 weeks (n = 34)	100 mg every 2 weeks (n = 34)	Combined (n = 137)	Total (n = 172)
Women, no. (%)	26 (74.3)	30 (85.7)	23 (67.6)	26 (76.5)	27 (79.4)	106 (77.4)	132 (76.7)
Age, years	52.0 (46.0, 66.0)	57.0 (50.0, 64.0)	48.0 (41.0, 63.0)	57.5 (47.0, 66.0)	53.5 (45.0, 65.0)	54.0 (46.0, 64.0)	53.5 (46.0, 64.5)
Disease duration, years	5.6 (1.4, 10.9)	8.2 (4.1, 14.3)	8.2 (2.9, 12.8)	6.3 (3.4, 14.1)	9.0 (4.1, 14.2)	8.2 (3.4, 13.9)	7.8 (3.0, 13.3)
No. of swollen joints, 0–66	13 (10, 18)	14 (10, 21)	14 (7, 26)	20 (12, 26)	14 (11, 21)	15 (10, 24)	15 (10, 22)
No. of tender joints, 0–68	22 (16, 38)	28 (18, 40)	28 (9, 42)	32 (21, 44)	22 (16, 32)	27 (16, 40)	26 (16, 40)
Patient's assessment of pain, 0–10-cm VAS	7.0 (5.1, 7.9)	7.0 (6.3, 8.6)	6.7 (4.5, 7.4)	6.9 (5.3, 8.2)	5.2 (4.2, 7.5)	6.6 (4.9, 8.0)	6.8 (5.0, 8.0)
Patient's global assessment of disease activity, 0–10-cm VAS	6.6 (5.1, 7.8)	6.9 (4.5, 8.7)	6.6 (4.6, 7.5)	6.5 (4.8, 8.0)	5.3 (4.0, 7.7)	6.3 (4.3, 8.0)	6.5 (4.6, 8.0)
Evaluator's global assessment of disease activity, 0–10-cm VAS	5.9 (4.9, 6.9)	6.2 (5.0, 8.1)	6.7 (4.6, 7.1)	6.3 (5.2, 6.9)	6.3 (4.6, 7.2)	6.3 (5.0, 7.3)	6.2 (4.9, 7.1)
HAQ disability index, 0–3	1.3 (0.9, 1.9)	1.7 (1.4, 2.0)	1.6 (1.0, 2.0)	1.8 (0.9, 2.3)	1.3 (1.0, 1.8)	1.6 (1.1, 2.0)	1.6 (1.1, 2.0)
CRP level, mg/dl	2.0 (1.3, 3.4)	2.1 (1.2, 3.4)	1.6 (0.9, 2.7)	1.4 (0.9, 2.7)	1.6 (1.0, 3.0)	1.6 (1.0, 2.9)	1.7 (1.1, 3.0)
DAS28 using CRP level, 0–10	5.3 (4.5, 5.7)	5.3 (4.5, 6.2)	4.8 (4.1, 6.1)	5.4 (4.6, 6.4)	5.1 (4.2, 5.7)	5.1 (4.4, 5.9)	5.2 (4.4, 5.9)
DAS28 using ESR, 0–10	6.3 (5.7, 7.0)	6.4 (5.6, 7.3)	6.4 (5.2, 7.3)	6.7 (5.7, 7.3)	6.2 (5.5, 6.9)	6.4 (5.5, 7.2)	6.4 (5.6, 7.2)

Golimumab
κλινικές μελέτες σε PA (phase III)

ARD Online First, published on December 9, 2008 as 10.1136/ard.2008.099010

Golimumab, a Human Antibody to TNF-α Given by Monthly Subcutaneous Injections, in Active Rheumatoid Arthritis Despite Methotrexate: The GO-FORWARD Study

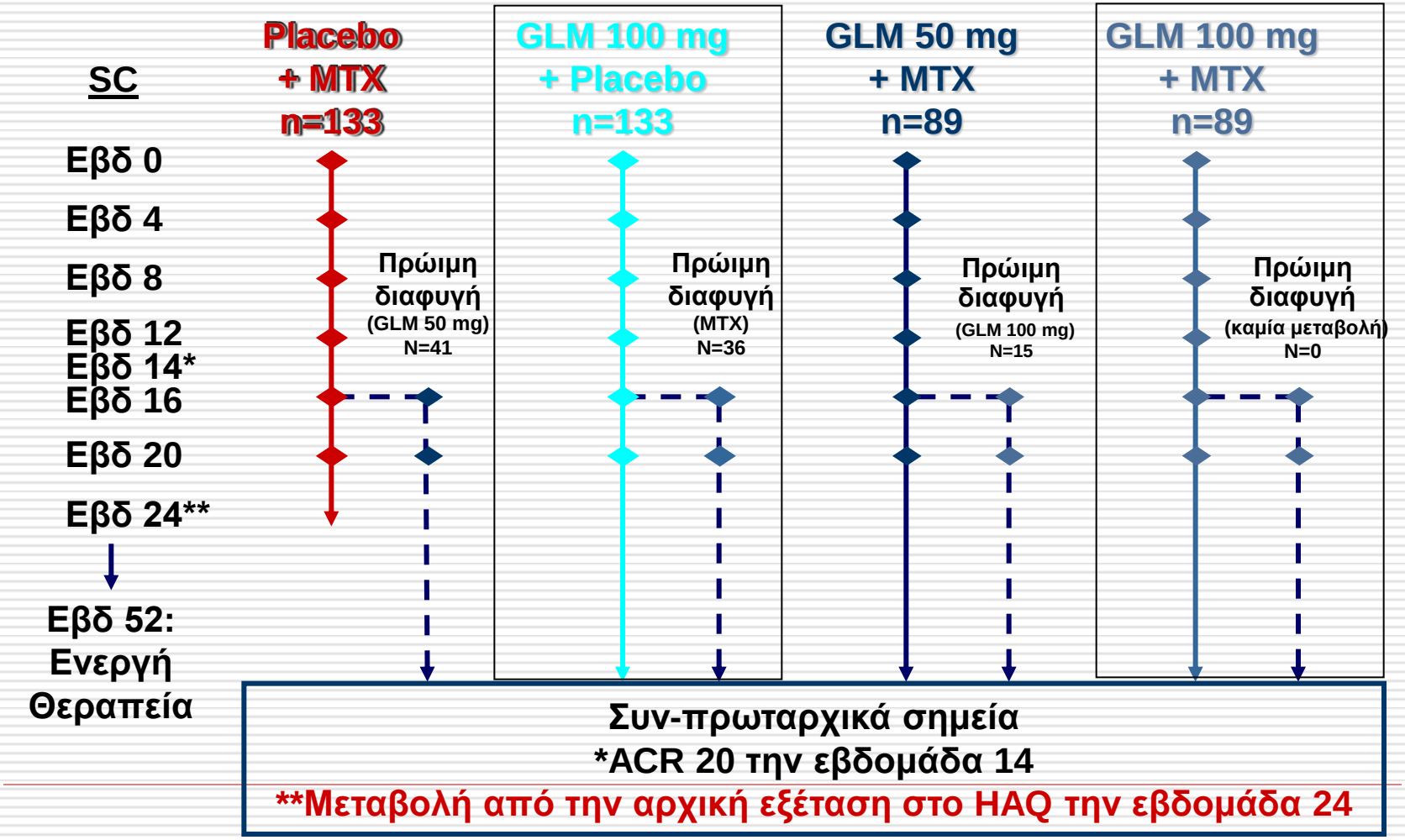
Edward C Keystone,[1] Mark C. Genovese,[2] Lars Klareskog,[3] Elizabeth C. Hsia,[4,5] Stephen T. Hall,[6] Pedro C. Miranda,[7] Jacek Pazdur,[8] Sang-Cheol Bae,[9] William Palmer,[10] Julie Zrubek,[4] Maria Wiekowski,[11] Sudha Visvanathan,[4] Zhong Wu,[4] Mahboob U. Rahman[4,5]

ARD Online First, published on December 9, 2008 as 10.1136/ard.2008.099010

Golimumab, a Human Antibody to TNF-α Given by Monthly Subcutaneous Injections, in Active Rheumatoid Arthritis Despite Methotrexate: The GO-FORWARD Study

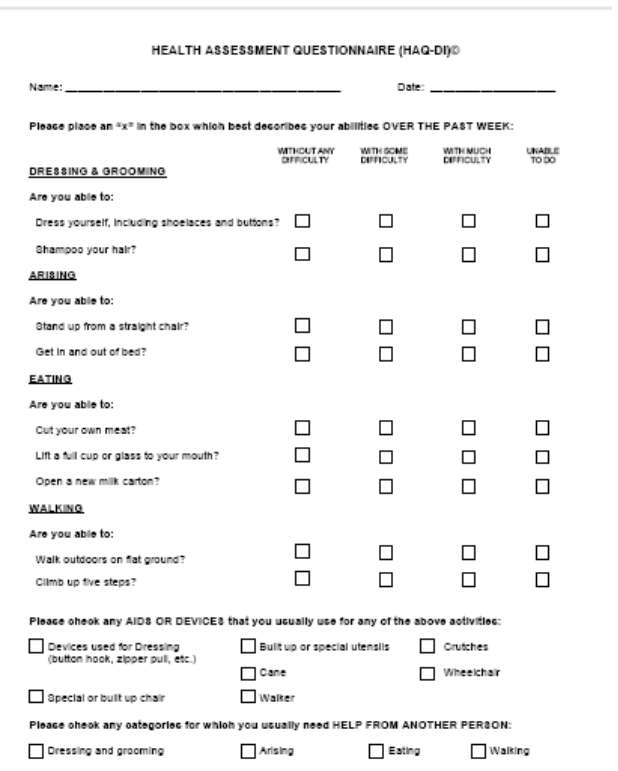
Characteristic	Group 1 Placebo + MTX	Group 2 Golimumab 100 mg + placebo	Golimumab + MTX		
			Group 3 50 mg	Group 4 100 mg	Groups 3 and 4 Combined
Patients randomized	133	133	89	89	178
Sex, n (%) women	109 (82.0%)	105 (78.9%)	72 (80.9%)	72 (80.9%)	144 (80.9%)
Age (yrs)	52.0 (42.0, 58.0)	51.0 (42.0, 59.0)	52.0 (43.0, 57.0)	50.0 (45.0, 56.0)	51.0 (44.0, 57.0)
Disease duration (yrs)	6.5 (3.1, 11.9)	5.9 (2.4, 12.2)	4.50 (2.1, 9.7)	6.70 (2.4, 14.3)	5.3 (2.1, 12.3)
No. of swollen joints (0-66)	12.0 (8.0, 19.0)	11.0 (8.0, 17.0)	13.0 (8.0, 22.0)	12.0 (8.0, 18.0)	12.5 (8.0, 18.0)
No. of tender joints (0-68)	21.0 (14.0, 34.0)	22.0 (14.0, 32.0)	26.0 (16.0, 39.0)	23.0 (15.0, 33.0)	24.5 (15.0, 37.0)
Anti-CCP antibodies	107 (80.5%)	106 (79.7%)	72 (80.9%)	68 (76.4%)	140 (78.7%)
Rheumatoid factor	108 (81.2%)	111 (83.5%)	77 (86.5%)	75 (84.3%)	152 (85.4%)
Patient assessment of pain (VAS, 0-10 cm)	5.70 (3.60, 7.50)	6.00 (4.50, 7.40)	6.10 (4.70, 7.70)	6.40 (4.60, 8.00)	6.35 (4.60, 8.00)
Patient global assessment of disease activity (VAS, 0-10 cm)	5.30 (3.70, 7.20)	5.60 (3.60, 7.40)	6.00 (3.80, 7.90)	5.90 (4.10, 7.70)	5.95 (3.90, 7.80)
Evaluator global assessment of disease activity (VAS, 0-10 cm)	5.65 (4.30, 6.85)	5.80 (4.40, 6.80)	6.10 (5.10, 7.10)	6.10 (4.30, 7.00)	6.10 (4.70, 7.10)
HAQ-DI (0-3)	1.250 (0.750, 1.750)	1.375 (0.875, 1.8750	1.375 (1.000, 1.875)	1.375 (0.875, 1.875)	1.375 (0.875, 1.875)
CRP (mg/dL)	0.80 (0.30, 2.00)	0.90 (0.40, 2.50)	1.00 (0.40, 2.80)	0.90 (0.40, 2.40)	0.95 (0.40, 2.40)
DAS28 using CRP	4.860 (4.194, 5.480)	4.803 (4.151, 5.558)	5.100 (4.060, 5.651)	4.902 (4.320, 5.521)	4.931 (4.174, 5.598)
DAS28 using ESR	6.111 (5.260, 6.574)	6.013 (5.198, 6.800)	6.105 (5.366, 6.940)	5.905 (5.292, 6.805)	6.008 (5.330, 6.843)
MTX dose (mg/week)	15.0 (15.0, 20.0)	15.0 (15.0, 20.0)	15.0 (15.0, 20.0)	15.0 (15.0, 20.0)	15.0 (15.0, 20.0)
Duration of previous MTX use					

Ασθενείς με ενεργό ΡΑ παρά τη θεραπεία με MTX (n=444)



Keystone E *et al.*, 2009 Ann Rheum Dis 68:789-796.

HAQ DI



HEALTH ASSESSMENT QUESTIONNAIRE (HAQ-DI)©

Name: _____ Date: _____

Please place an "x" in the box which best describes your abilities OVER THE PAST WEEK:

	WITHOUT ANY DIFFICULTY	WITH SOME DIFFICULTY	WITH MUCH DIFFICULTY	UNABLE TO DO
DRESSING & GROOMING				
Are you able to:				
Dress yourself, including shoelaces and buttons?	☐	☐	☐	☐
Shampoo your hair?	☐	☐	☐	☐
ARISING				
Are you able to:				
Stand up from a straight chair?	☐	☐	☐	☐
Get in and out of bed?	☐	☐	☐	☐
EATING				
Are you able to:				
Cut your own meat?	☐	☐	☐	☐
Lift a full cup or glass to your mouth?	☐	☐	☐	☐
Open a new milk carton?	☐	☐	☐	☐
WALKING				
Are you able to:				
Walk outdoors on flat ground?	☐	☐	☐	☐
Climb up five steps?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of the above activities:

☐ Devices used for Dressing (button hook, zipper pull, etc.)
☐ Built up or special utensils
☐ Crutches
☐ Cane
☐ Wheelchair
☐ Special or built up chair
☐ Walker

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

☐ Dressing and grooming ☐ Arising ☐ Eating ☐ Walking

-1-

Please place an "x" in the box which best describes your abilities OVER THE PAST WEEK:

	WITHOUT ANY DIFFICULTY	WITH SOME DIFFICULTY	WITH MUCH DIFFICULTY	UNABLE TO DO
HYGIENE				
Are you able to:				
Wash and dry your body?	☐	☐	☐	☐
Take a tub bath?	☐	☐	☐	☐
Get on and off the toilet?	☐	☐	☐	☐
REACH				
Are you able to:				
Reach and get down a 5 pound object (such as a bag of sugar) from above your head?	☐	☐	☐	☐
Bend down to pick up clothing from the floor?	☐	☐	☐	☐
GRIP				
Are you able to:				
Open car doors?	☐	☐	☐	☐
Open previously opened jars?	☐	☐	☐	☐
Turn faucets on and off?	☐	☐	☐	☐
ACTIVITIES				
Are you able to:				
Run errands and shop?	☐	☐	☐	☐
Get in and out of a car?	☐	☐	☐	☐
Do chores such as vacuuming or yard work?	☐	☐	☐	☐

Please check any AIDS OR DEVICES that you usually use for any of the above activities:

☐ Raised toilet seat
☐ Bathtub bar
☐ Long-handled appliances for reach
☐ Bathtub seat
☐ Long-handled appliances in bathroom
☐ Jar opener (for jars previously opened)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

☐ Hygiene ☐ Reach ☐ Gripping and opening things ☐ Errands and chores

-2-

Your ACTIVITIES: To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?

COMPLETELY	MOSTLY	MODERATELY	A LITTLE	NOT AT ALL
☐	☐	☐	☐	☐

Your PAIN: How much pain have you had IN THE PAST WEEK?
On a scale of 0 to 100 (where zero represents "no pain" and 100 represents "severe pain"), please record the number below.

☐☐☐

Your HEALTH: Please rate how well you are doing on a scale of 0 to 100 (0 represents "very well" and 100 represents "very poor" health), please record the number below.

☐☐☐

-3-

http://www.4s-dawn.com/HAQ/HAQ-DI.html

ARD Online First, published on December 9, 2008 as 10.1136/ard.2008.099010

Golimumab, a Human Antibody to TNF-α Given by Monthly Subcutaneous Injections, in Active Rheumatoid Arthritis Despite Methotrexate: The GO-FORWARD Study

Assessment	Group 1 Placebo + MTX	Group 2 Golimumab 100 mg + placebo	Golimumab + MTX Group 3 50 mg	Golimumab + MTX Group 4 100 mg	Golimumab + MTX Groups 3 and 4 Combined
Patients randomized	133	133	89	89	178
Primary Endpoints					
ACR 20 at week 14	44 (33.1%)	59 (44.4%)	49 (55.1%)	50 (56.2%)	99 (55.6%)
p-value		0.059	0.001	< 0.001	< 0.001
Improvement from baseline in HAQ-DI at week 24	-0.13 (-0.38, 0.13)	-0.13 (-0.63, 0.25)	-0.38 (-0.75, -0.13)	-0.50 (-0.75, -0.13)	-0.44 (-0.75, -0.13)
p-value		0.240	< 0.001	< 0.001	< 0.001
Secondary Endpoints					
Week 14					
ACR 50	13 (9.8%)	27 (20.3%)	31 (34.8%)	26 (29.2%)	57 (32.0%)
p-value		0.016	< 0.001	< 0.001	< 0.001
ACR 70	5 (3.8%)	10 (7.5%)	12 (13.5%)	8 (9.0%)	20 (11.2%)
p-value		0.184	0.008	0.104	0.016
ACR 90	1 (0.8%)	1 (0.8%)	2 (2.2%)	0 (0.0%)	2 (1.1%)
p-value		1.000	0.344	0.412	0.740
ACR-N	0.00 (-28.60, 25.50)	10.50 (-11.80, 42.60)	28.20 (0.00, 60.00)	25.00 (0.00, 54.50)	27.30 (0.00, 56.30)
p-value		0.042	< 0.001	< 0.001	< 0.001
Improvement from baseline in HAQ-DI	-0.13 (-0.38, 0.13)	-0.25 (-0.63, 0.13)	-0.38 (-0.75, -0.13)	-0.38 (-0.63, -0.13)	-0.38 (-0.75, -0.13)
p-value		0.097	< 0.001	< 0.001	< 0.001
EULAR responders (DAS28 calculated using ESR)	59 (44.4%)	79 (59.4%)	63 (70.8%)	67 (75.3%)	130 (73.0%)
p-value		0.014	< 0.001	< 0.001	< 0.001
DAS28 (ESR) remission	2 (1.5%)	11 (8.3%)	14 (15.7%)	16 (18.0%)	30 (16.9%)

Golimumab
κλινικές μελέτες σε PA (phase III)

ARD

Golimumab in patients with active rheumatoid arthritis despite methotrexate therapy: 52-week results of the *GO-FORWARD* study

Edward Keystone, Mark C Genovese, Lars Klareskog, et al.

Ann Rheum Dis published online May 5, 2010
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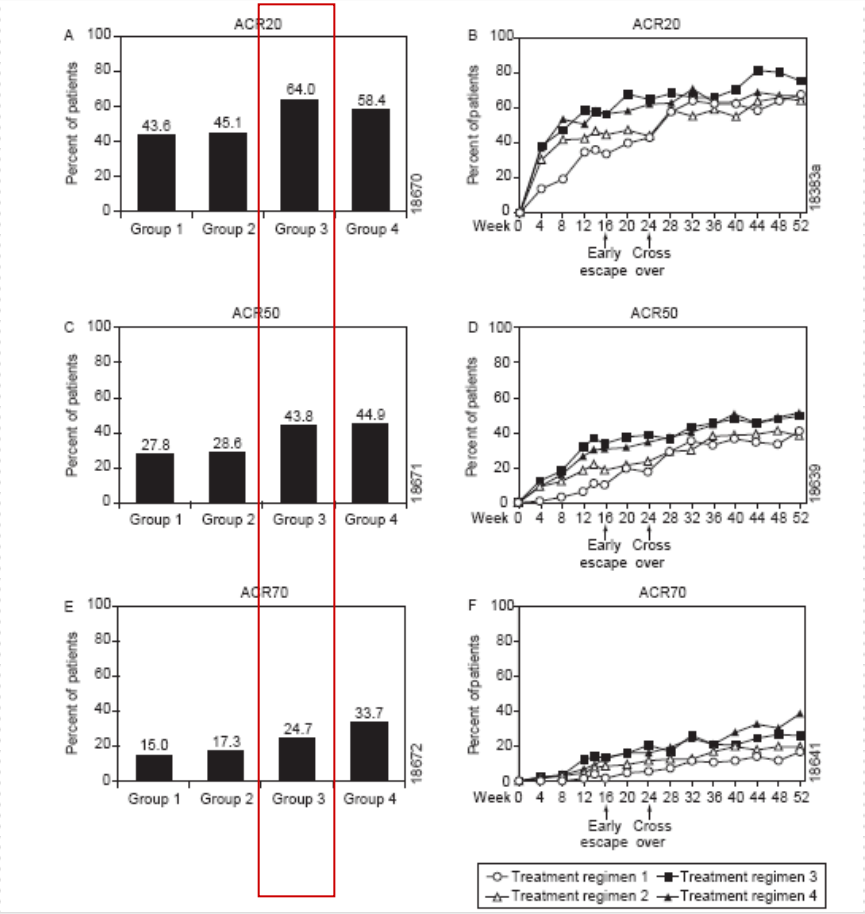

Keystone et al. Ann Rheum Dis 2010;69:1129–1135. Epub 2010 May 5

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	Group 1: placebo+MTX → golimumab 50 mg+MTX*		Group 2: golimumab 100 mg+placebo		Group 3: golimumab 50 mg+MTX		Group 4: golimumab 100 mg+MTX	
	Early escape (weeks 16–52)	Crossover (weeks 24–52)	100 mg+ placebo only	Early escape (weeks 16–52) 100 mg → 100 mg+ MTX	50 mg+ MTX only	Early escape (weeks 16–52) 50 mg+ MTX→ 100 mg+MTX	100 mg+ MTX only	Early escape (weeks 16–52) 100 mg+ MTX → 100 mg+MTX
Patients (n)	42	82	97	36	74	15	75	14
Patients with evaluable data for ACR calculation (n)	39	81	87	31	70	15	65	14
ACR20 (%)	23 (59.0)	58 (71.6)	60 (69.0)	15 (48.4)	58 (82.9)	6 (40.0)	45 (69.2)	7 (50.0)
ACR50 (%)	12 (30.8)	37 (45.7)	38 (43.7)	7 (22.6)	40 (57.1)	2 (13.3)	36 (55.4)	4 (28.6)
ACR70 (%)	7 (17.9)	20 (24.7)	23 (26.4)	4 (12.9)	22 (31.4)	0 (0)	29 (44.6)	1 (7.1)
ACR-N	25.0 (−10.1, 64.3)	46.2 (14.3, 69.7)	33.3 (15.2, 72.0)	13.8 (0.0, 47.5)	54.4 (27.3, 76.5)	6.7 (−16.7, 25.0)	56.0 (7.7, 81.5)	31.5 (6.3, 55.0)
% Reduction in swollen joints	69.2 (20.0, 85.7)	85.7 (60.0, 100)	80.0 (63.6, 100)	75.3 (20.7, 100)	84.9 (62.5, 100)	36.4 (17.6, 54.5)	94.4 (73.3, 100)	56.3 (48.0, 81.4)
% Reduction in tender joints	40.0 (17.2, 80.0)	76.5 (52.2, 93.3)	84.0 (62.1, 93.8)	57.1 (37.0, 84.4)	80.8 (55.9, 100)	26.5 (0, 73.9)	85.7 (70.3, 100)	62.5 (37.9, 73.7)
Patients with zero tender and swollen joints at week 24 (%)	0 (0)	2 (2.4)	9 (9.8)	0 (0)	8 (11.0)	0 (0)	7 (9.6)	0 (0)
Patients with zero tender and swollen joints at week 52 (%)	2 (5.1)	10 (12.3)	14 (16.1)	1 (3.1)	15 (21.4)	0 (0)	16 (24.6)	0 (0)
CRP (mg/dl)	20.0 (0.0, 70.0)	40.0 (0.0, 68.4)	25.0 (0.0, 66.7)	32.5 (0.0, 76.4)	35.7 (0.0, 77.8)	56.4 (0.0, 87.1)	50.0 (0.0, 81.3)	52.7 (12.5, 78.9)
HAQ-DI (actual improvement)	0.25 (0.00, 0.75)	0.38 (0.13, 0.88)	0.38 (0.00, 1.00)	0.38 (0.00, 0.63)	0.63 (0.25, 0.88)	0.38 (0.13, 1.00)	0.50 (0.25, 1.0)	0.25 (−0.25, 0.50)
Patients with HAQ-DI improvement ≥0.25 (%)	22 (56.4)	55 (67.9)	53 (60.9)	17 (54.8)	53 (76.8)	11 (73.3)	51 (78.5)	7 (53.8)
EULAR (DAS28 using ESR) responders (%)	25 (64.1)	68 (84.0)	75 (86.2)	23 (74.2)	63 (92.6)	10 (66.7)	55 (88.7)	11 (84.6)
EULAR (DAS28 using CRP) responders (%)	26 (66.7)	69 (86.3)	79 (91.9)	23 (74.2)	64 (91.4)	13 (92.9)	58 (89.2)	11 (91.7)
DAS28 (using ESR) low disease activity (≤3.2) (%)	9 (23.1)	32 (39.5)	30 (34.5)	7 (22.6)	33 (48.5)	2 (13.3)	36 (57.1)	4 (30.8)
DAS28 (using CRP) low disease activity (≤3.2) (%)	19 (48.7)	59 (73.8)	56 (65.1)	19 (61.3)	49 (70.0)	5 (35.7)	47 (72.3)	3 (25.0)
DAS28 (using ESR) remission (≤2.6) (%)	7 (17.9)	21 (25.9)	20 (23.0)	2 (6.5)	25 (36.8)	1 (6.7)	24 (38.1)	2 (15.4)
DAS28 (using CRP) remission (≤2.6) (%)	11 (28.2)	41 (51.3)	38 (44.2)	12 (38.7)	43 (61.4)	4 (28.6)	39 (60.0)	3 (25.0)

ARD

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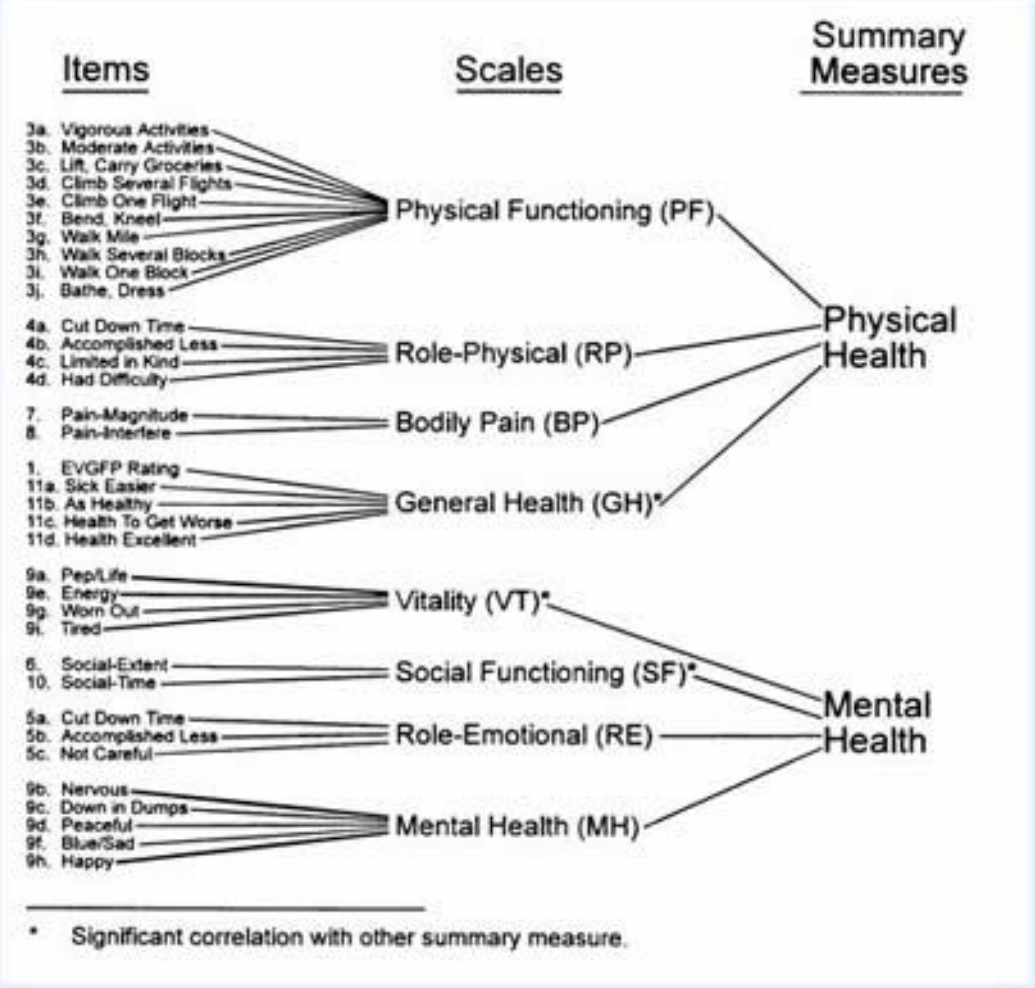
Impact of Golimumab On Physical Function, Health-Related Quality of Life, Productivity and Employment in Rheumatoid Arthritis Patients: Week 52 Results From GO-FORWARD

- Physical function was assessed using HAQ disability index and SF-36 PCS score.
- HRQoL was assessed using the PCS and MCS scores of the SF-36
- Productivity was assessed on a 10-cm VAS.

M.C. Genovese *et al* ***Presentation Number:*** *1670* ***Poster Board Number:*** *403*

SF-36® Measurement Model

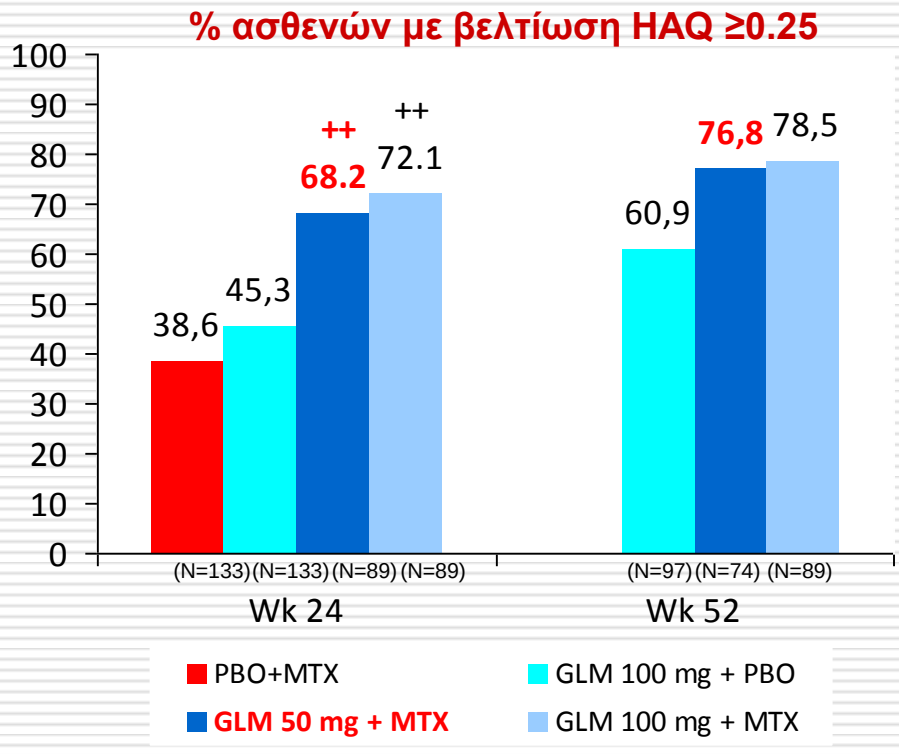


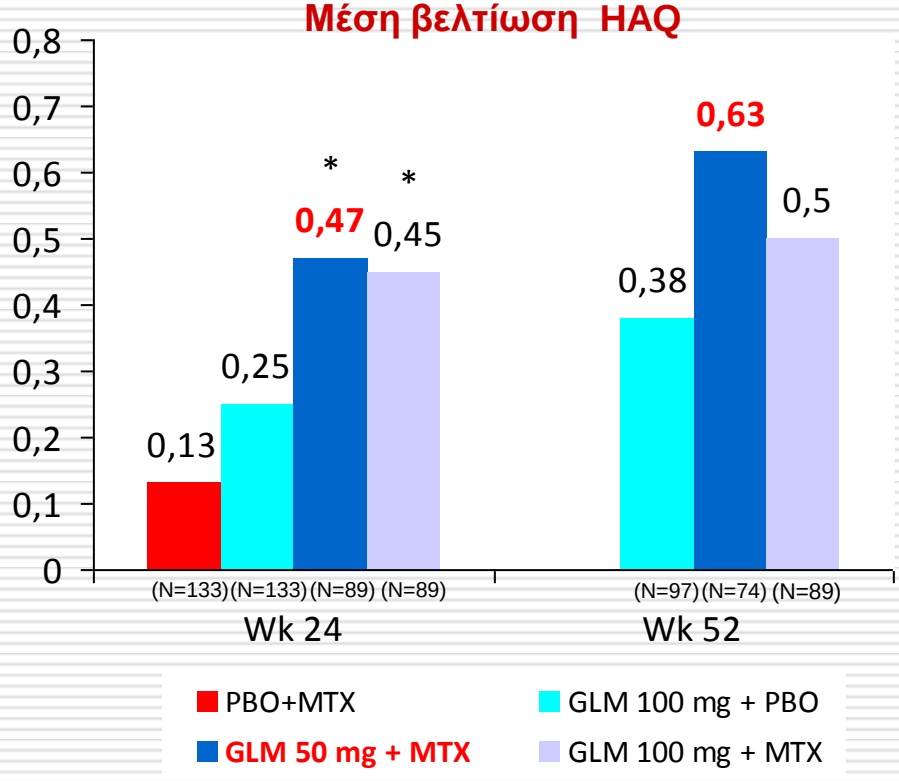
Impact of Golimumab On Physical Function, Health-Related Quality of Life, Productivity and Employment in Rheumatoid Arthritis Patients: Week 52 Results From GO-FORWARD

	PBO + MTX	GLM 100 mg + PBO	GLM 50 mg + MTX	GLM 100 mg + MTX
Wk24, N	133	133	89	89
HAQ improvement	0.13±0.58	0.24±0.66	0.47 ± 0.55*	0.45±0.52*
HAQ ≥0.25 improvement	38.6%	45.3%	68.2%++	72.1%++
SF-36 PCS change	2.5±8.1	4.7±8.8	8.3±8.3*	7.0±7.8*
SF-36 MCS change	0.8±9.7	3.4±10.2†	1.8±10.9	4.3±10.7†
Productivity[b] change	-0.45±2.98	-1.08±3.04	-2.0±3.1*	-2.0±2.5*
Time lost from work by pt during past 4 wks (days)[c]	5.7±19.7	1.1±2.2	0.8±3.1†	5.8±12.2
Week 52, N[d]	-	97	74	89
HAQ improvement	-	0.49±0.66	0.61±0.64	0.51±0.56
HAQ ≥0.25 improvement	-	60.9%	76.8%	74.4%
SF-36 PCS change	-	7.2 ±9.7	8.9±9.1	9.5±9.0
SF-36 MCS change	-	3.4±10.2	3.7±9.4	5.5±11.2

*p<0.001, †p<0.05, ++p<0.0001

Σημαντική βελτίωση της σωματικής λειτουργίας στις 24 και 52 εβδομάδες θεραπείας





***p<0.001**
++p<0.0001
Την εβδ. 52 δεν συγκρίθηκαν οι ομάδες μεταξύ τους

Genovese et al. ACR 2009. Abstract 1670
Keystone et al. Ann Rheum Dis 2010;69:1129–1135. Epub 2010 May 5

Assessing HRQoL Burden of Disease and Comparison to the U.S. Population in RA Patients Treated with Golimumab: Results From the GO-FORWARD Trial

Monday, October 19, 2009: 9:00 AM - 11:00 AM

Hall D (Pennsylvania Convention Center)

***G. Hammond**, Lincoln, RI, A. Raju, S. Parasuraman, J. Buchanan and T. Gathany, Johnson and Johnson Pharmaceutical Services, LLC, Malvern, PA*

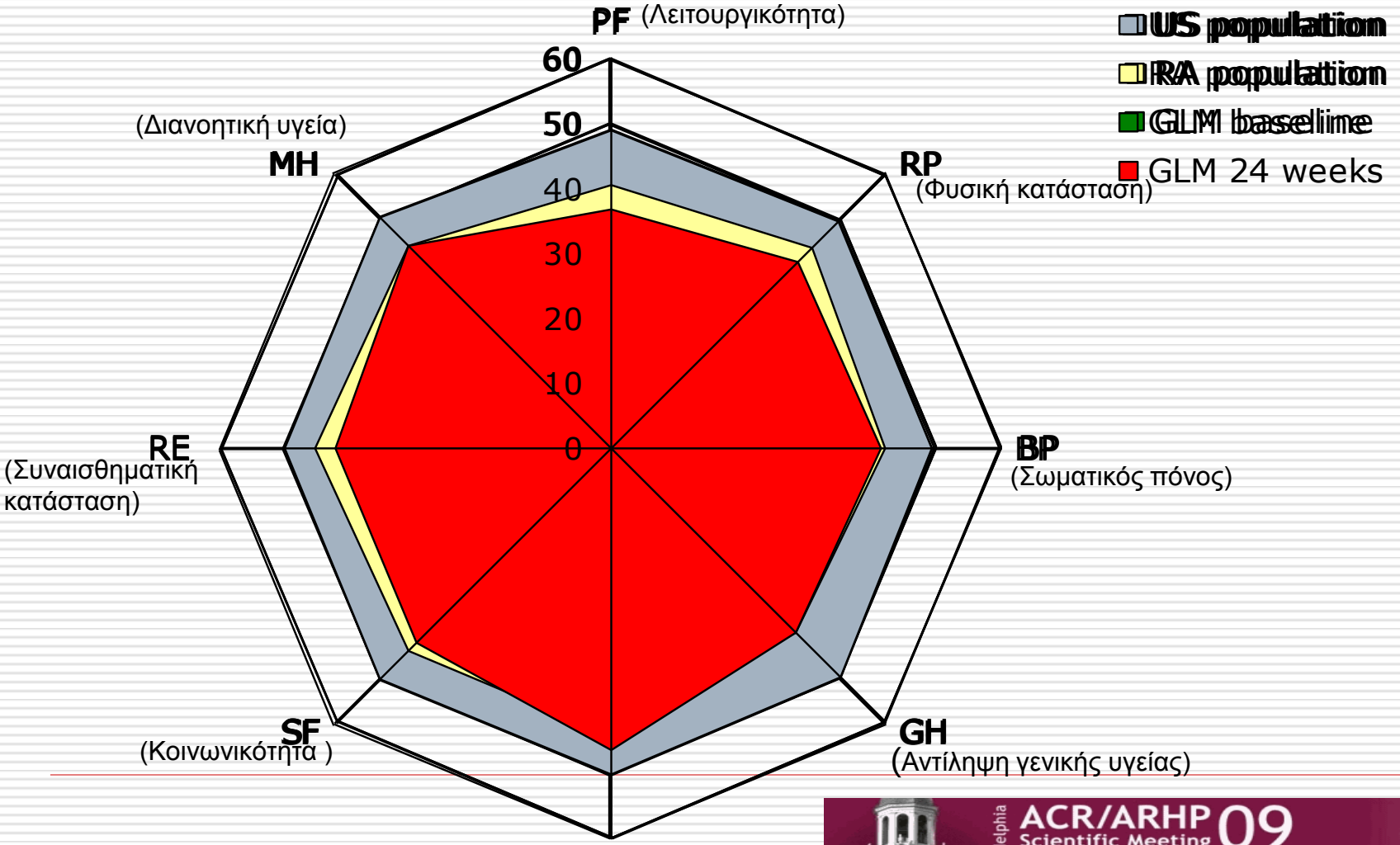
Presentation Number: 731

Poster Board Number: 82

Assessing HRQoL Burden of Disease and Comparison to the U.S. Population in RA Patients Treated with Golimumab: Results From the GO-FORWARD Trial

	GO-FORWARD		Norms			Significance Testing		
	Baseline (n=442)	Wk 14 (n=429)	U.S. Pop. (n=2031)	Heart Disease (n=188)	Rheumatoid (n=136)	U.S. Pop.	Heart Disease	Rheumatoid
Scales	Mean	Mean	Mean	Mean	Mean	Mean Diff. (Comparator-Trial)		
PF	32.5	36.8	48.7	40.3	42.2	11.9**	3.5*	5.5**
RP	34.8	40.5	49.5	43.6	43.2	9.0**	3.1*	2.8
BP	35.6	41.5	49.2	41.9	41.6	7.7**	0.5	0.1
GH	37.3	39.7	49.8	39.9	42.5	10.1**	0.2	2.8*
VT	41.6	46.2	50.2	44.3	46.1	4.0**	-1.9	-0.1
SF	38.2	42.4	49.9	44.2	44.7	7.5**	1.8	2.3
RE	39.0	42.3	50.2	45.5	45.5	7.9**	3.2*	3.2
MH	40.5	43.7	49.9	44.3	46.6	6.2**	0.6	2.9*
PCS	33.5	38.6	49.0	40.7	41.3	10.4**	2.1	2.7*
MCS	43.0	45.9	50.5	46.5	47.6	4.6**	0.6	1.7

Βελτίωση της ποιότητας ζωής με Golimumab στις 24 εβδομάδες



Philadelphia ACR/ARHP 09 Scientific Meeting
Pre-Conference Courses: October 16-17, 2009
Annual Scientific Sessions: October 17-21, 2009

EMPLOYABILITY-ADJUSTED-LIFE-YEARS IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH GOLIMUMAB PLUS MTX OR MTX ALONE

- HAQ : 1,36 (BL) => 0,92 (24 w) => 0.88 (160 w)
- 33% (Gol) vs 15% (MTX) των ασθενών που δεν εργαζόταν => εργάζονται
- In the logistic regression model by using the derived HAQ score, age, and gender, in the base case scenarios, over 10 years period for a RA patient cohort with an average of 50 years of age,
  - GLM-treated patients had expected **employability** adjusted life years of 5.92 for females and 7.15 for males
  - 4.96 for females and 6.28 for males in MTX-treated patients

Golimumab
κλινικές μελέτες σε PA (phase III)

ARTHRITIS & RHEUMATISM
Vol. 60, No. 8, August 2009, pp 2272–2283
DOI 10.1002/art.24638
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Golimumab, a Human Anti–Tumor Necrosis Factor α Monoclonal Antibody, Injected Subcutaneously Every Four Weeks in Methotrexate-Naive Patients With Active Rheumatoid Arthritis

Twenty-Four–Week Results of a Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Golimumab Before Methotrexate as First-Line Therapy for Early-Onset Rheumatoid Arthritis

Paul Emery,[1] Roy M. Fleischmann,[2] Larry W. Moreland,[3] Elizabeth C. Hsia,[4] Ingrid Strusberg,[5] Patrick Durez,[6] Peter Nash,[7] Eric Jason B. Amante,[8] Melvin Churchill,[9] Won Park,[10] Bernardo Antonio Pons-Estel,[11] Mittie K. Doyle,[4] Sudha Visvanathan,[12] Weichun Xu,[12] and Mahboob U. Rahman[4]

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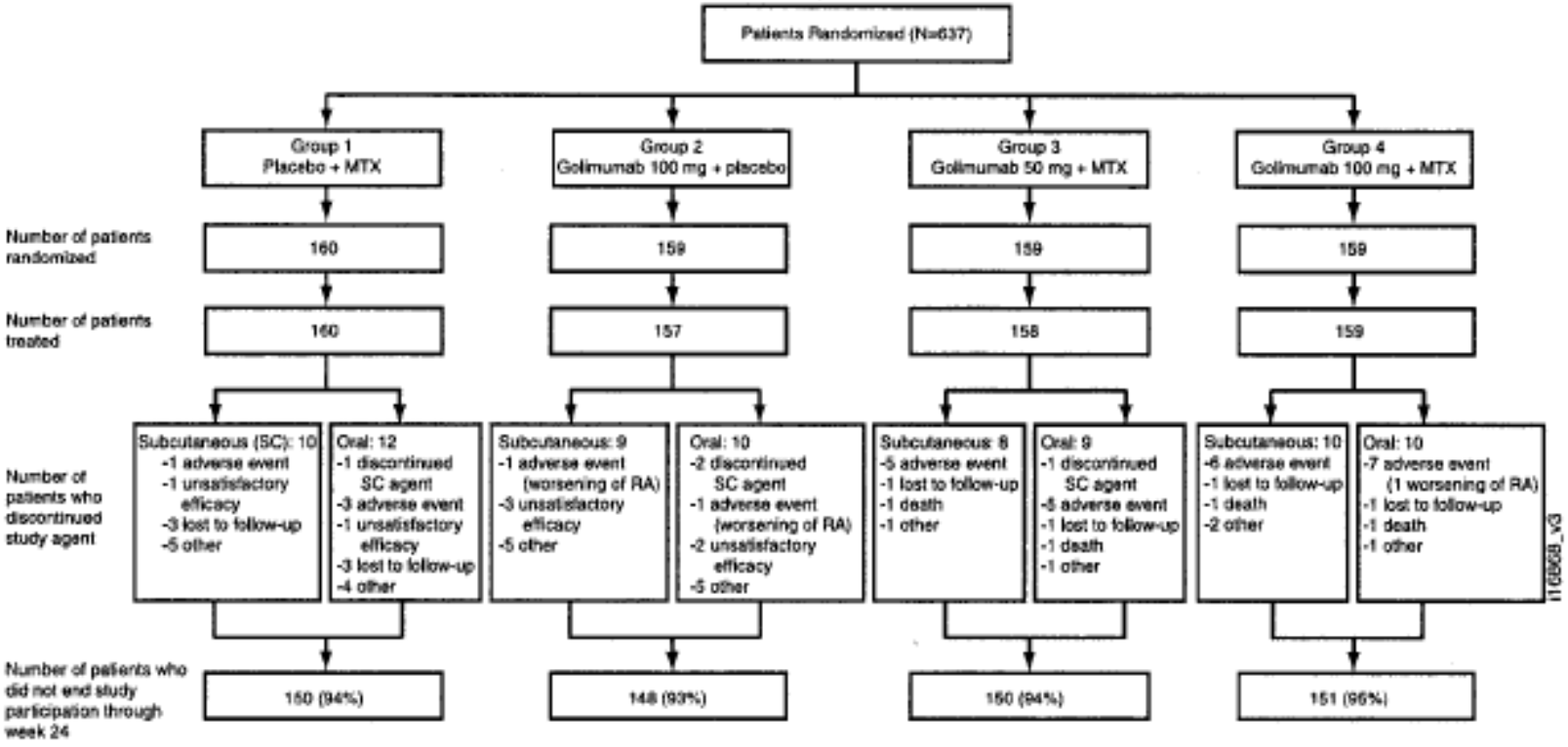

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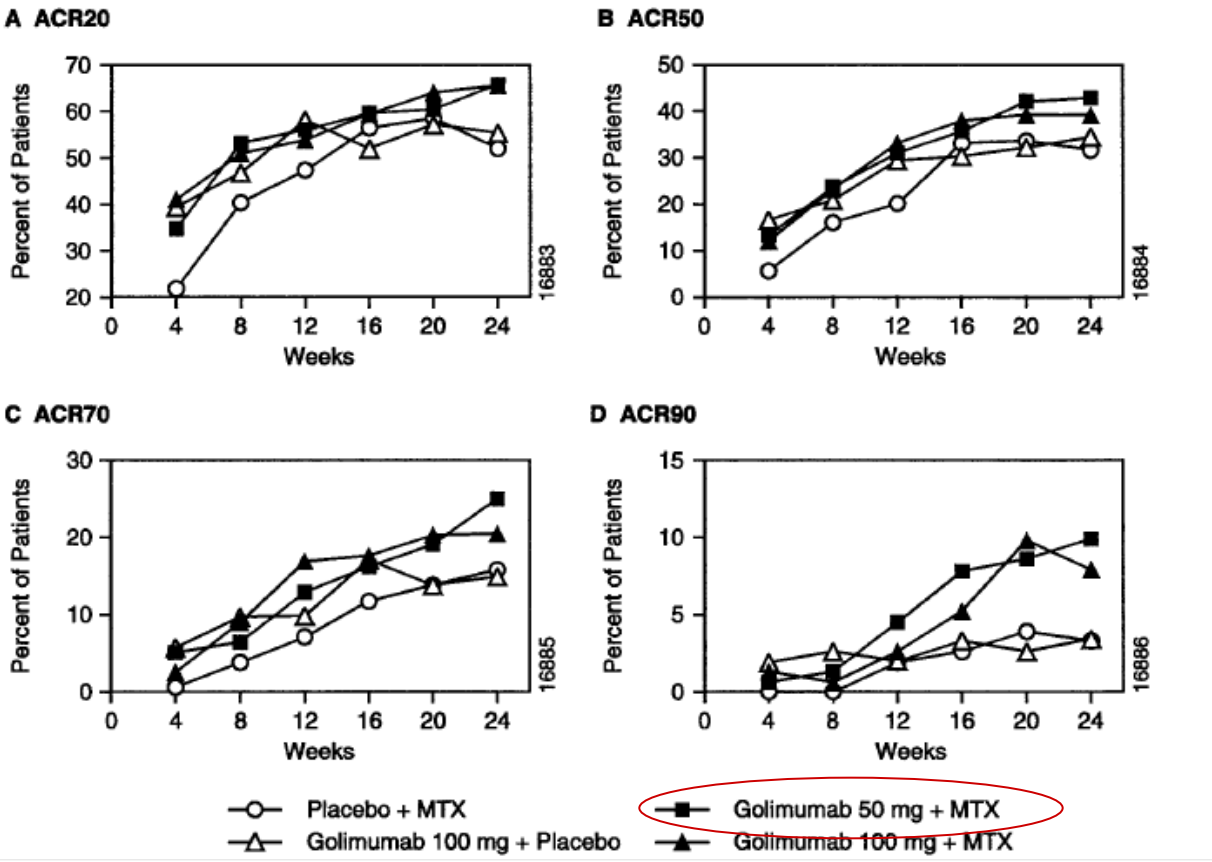
Ανταπόκριση ACR στους 6 μήνες



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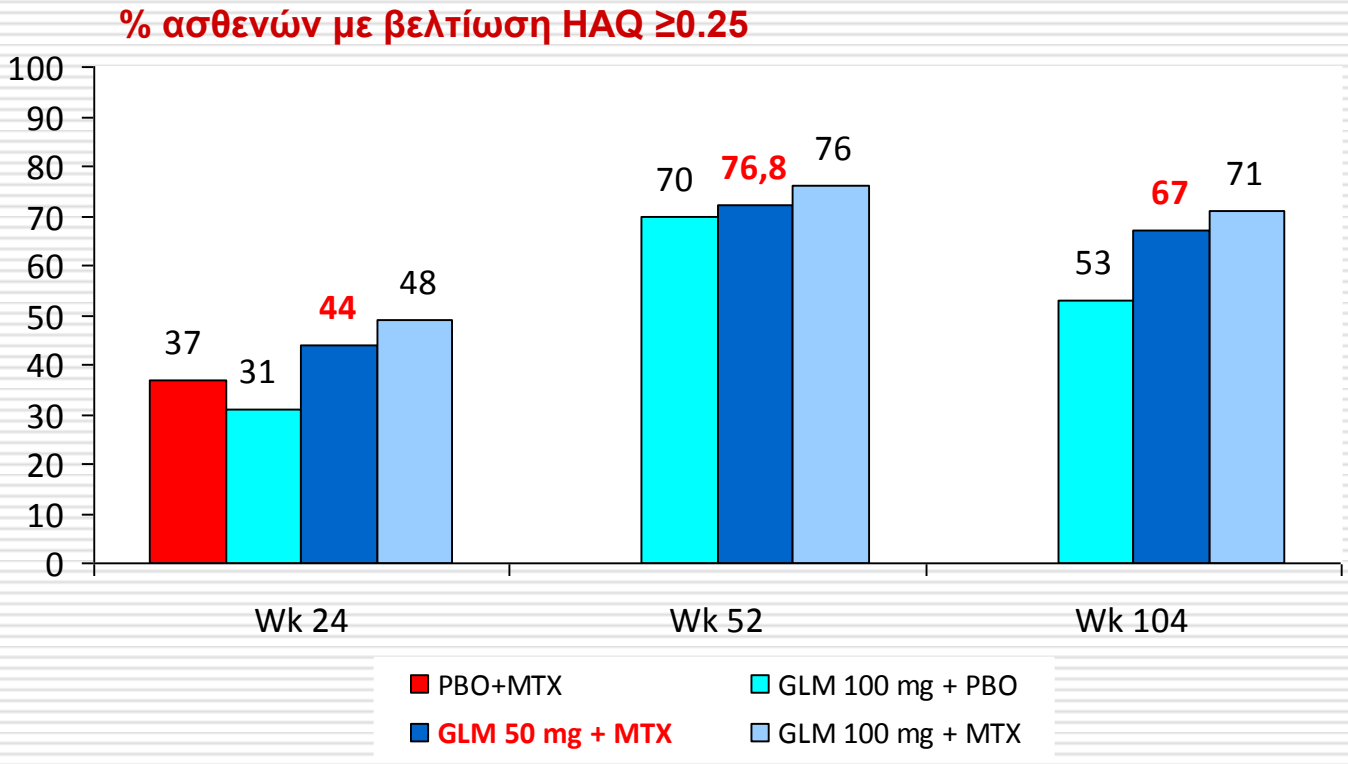
	Group 1, placebo plus MTX (n = 160)	Group 2, golimumab 100 mg plus placebo (n = 159)	Group 3, golimumab 50 mg plus MTX (n = 159)	Group 4, golimumab 100 mg plus MTX (n = 159)	Groups 3 and 4 combined (n = 318)
ACR50 response, all randomized patients [*P*]	47 (29.4)	52 (32.7)	64 (40.3) [0.042]	58 (36.5) [0.177]	122 (38.4) [0.053]
Patients with CRP level <1.5 mg/dl at screening	21/83 (25.3)	30/80 (37.5)	33/82 (40.2)	24/82 (29.3)	57/164 (34.8)
Patients with CRP level ≥1.5 mg/dl at screening	26/77 (33.8)	22/79 (27.8)	31/77 (40.3)	34/77 (44.2)	65/154 (42.2)
ACR50 response, post hoc analysis of all treated patients [*P*]†	47/160 (29.4)	52/157 (33.1)	64/158 (40.5) [0.038]	58/159 (36.5) [0.177]	122/317 (38.5) [0.049]
ACR50 response, all randomized patients with abnormal baseline CRP level [*P*]‡	34/95 (35.8)	26/90 (28.9)	38/86 (44.2) [0.250]	37/83 (44.6) [0.240]	75/169 (44.4) [0.178]
ACR50 response, all randomized patients with CRP level <0.3 mg/dl assigned to 0.15 mg/dl instead of 0.3 mg/dl, post hoc analysis [*P*]	47 (29.4)	53 (33.3)	64 (40.3) [0.042]	60 (37.7) [0.114]	124 (39.0) [0.039]
ACR20 response, all randomized patients [*P*]	79 (49.4)	82 (51.6)	98 (61.6) [0.028]	98 (61.6) [0.028]	196 (61.6) [0.011]
ACR70 response, all randomized patients [*P*]	25 (15.6)	22 (13.8)	38 (23.9) [0.064]	29 (18.2) [0.535]	67 (21.1) [0.155]
ACR90 response, all randomized patients [*P*]	5 (3.1)	5 (3.1)	15 (9.4) [0.021]	12 (7.5) [0.080]	27 (8.5) [0.027]
ACR-N, median % improvement [*P*]	18.20	21.60	33.30 [0.015]	27.80 [0.095]	32.45 [0.017]
DAS28 using CRP level, good or moderate response [*P*]	97 (60.6)	105 (66.0)	120 (75.5) [0.005]	120 (75.5) [0.004]	240 (75.5) [<0.001]
DAS28 using ESR, good or moderate response [*P*]	98 (61.3)	107 (67.3)	116 (73.0) [0.027]	122 (76.7) [0.003]	238 (74.8) [0.002]
DAS28 using CRP level, remission [*P*]	45 (28.1)	40 (25.2)	61 (38.4) [0.050]	60 (37.7) [0.069]	121 (38.1) [0.031]
DAS28 using ESR, remission [*P*]	18 (11.3)	25 (15.7)	40 (25.2) [0.001]	31 (19.5) [0.040]	71 (22.3) [0.003]
Median % improvement from baseline [*P*]					
Swollen joint count	66.70	66.70	75.60 [0.127]	71.40 [0.293]	75.00 [0.133]
Tender joint count	57.10	57.10	67.20 [0.023]	66.70 [0.088]	66.70 [0.020]
Patient's assessment of pain	44.35	38.30	52.15 [0.028]	51.65 [0.038]	52.05 [0.013]
Patient's assessment of disease activity	36.70	34.70	49.55 [0.042]	51.55 [0.005]	50.40 [0.005]
Physician's assessment of disease activity	63.00	57.05	66.70 [0.206]	62.50 [0.480]	64.70 [0.257]
CRP level	42.90	25.00	57.10 [0.002]	62.50 [0.014]	57.60 [0.001]
HAQ disability index	36.95	31.05	43.65 [0.141]	48.55 [0.006]	45.85 [0.014]
Increase in Hgb level of ≥1 gm/dl from baseline [*P*]§	13/37 (35.1)	7/43 (16.3)	28/34 (58.8) [0.040]	26/37 (43.2) [0.585]	36/71 (50.7) [0.145]

LONG-TERM EFFICACY AND SAFETY OF GOLIMUMAB, A HUMAN ANTI-TNF ALPHA MONOCLONAL ANTIBODY, IN METHOTREXATE-NAÏVE RHEUMATOID ARTHRITIS PATIENTS: RESULTS FROM THE GO-BEFORE STUDY (104 w)

	Group 1*	Group 2*	Group 3*	Group 4*
Randomized pts (n)	160	159	159	159
ACR 20 Wk 52	101(63.1%)	104(65.4%)	109(68.6%)	112(70.4%)
Wk 104	109(68.1%)	89(56.0%)	111(69.8%)	116(73.0%)
ACR 50 Wk 52	65(40.6%)	70(44.0%)	69(43.4%)	81(50.9%)
Wk 104	84(52.5%)	65(40.9%)	84(52.8%)	84(52.8%)
ACR 70 Wk 52	39(24.4%)	39(24.5%)	45(28.3%)	52(32.7%)
Wk 104	56(35.0%)	49(30.8%)	59(37.1%)	61(38.4%)
DAS28 (CRP) Good/Mod Response Wk 52	119(74.4%)	128(80.5%)	128(80.5%)	129(81.1%)
Wk 104	123(76.9%)	105(66.0%)	127(79.9%)	128(80.5%)
DAS28 (CRP) Remission Wk 52	62(38.8%)	60(37.7%)	72(45.3%)	75(47.2%)
Wk 104	77(48.1%)	66(41.5%)	86(54.1%)	82(51.6%)
Proportion with HAQ improvement ≥0.25 Wk 52	114(71.7%)	109(69.9%)	113(72.4%)	120(76.4%)
WK 104	114(71.7%)	83(53.2%)	104(66.7%)	112(71.3%)

R.M. Fleischmann Ann Rheum Dis 2010;69(Suppl3):681

Βελτίωση της σωματικής λειτουργίας από τις 24 ως τις 104 εβδομάδες θεραπείας (Go Before study)



***p<0.001**
++p<0.0001
Την εβδ. 52 δεν συγκρίθηκαν οι ομάδες μεταξύ τους

Emery P et al, Arthritis & Rheum, 2009;60:2272-2283
Fleischmann R et al, Ann Rheum Dis 2010;69(Suppl3):681.

Golimumab
κλινικές μελέτες σε PA (phase III)

Golimumab in patients with active rheumatoid arthritis after treatment with tumour necrosis factor α inhibitors (GO-AFTER study): a multicentre, randomised, double-blind, placebo-controlled, phase III trial

*Josef S Smolen, Jonathan Kay, Mittie K Doyle, Robert Landewé, Eric L Matteson, Jürgen Wollenhaupt, Norman Gaylis, Frederick T Murphy, Jeffrey S Neal, Yiying Zhou, Sudha Visvanathan, Elizabeth C Hsia, Mahboob U Rahman, for the GO-AFTER study investigators**

www.thelancet.com Published online June 29, 2009 DOI:10.1016/S0140-6736(09)60506-7

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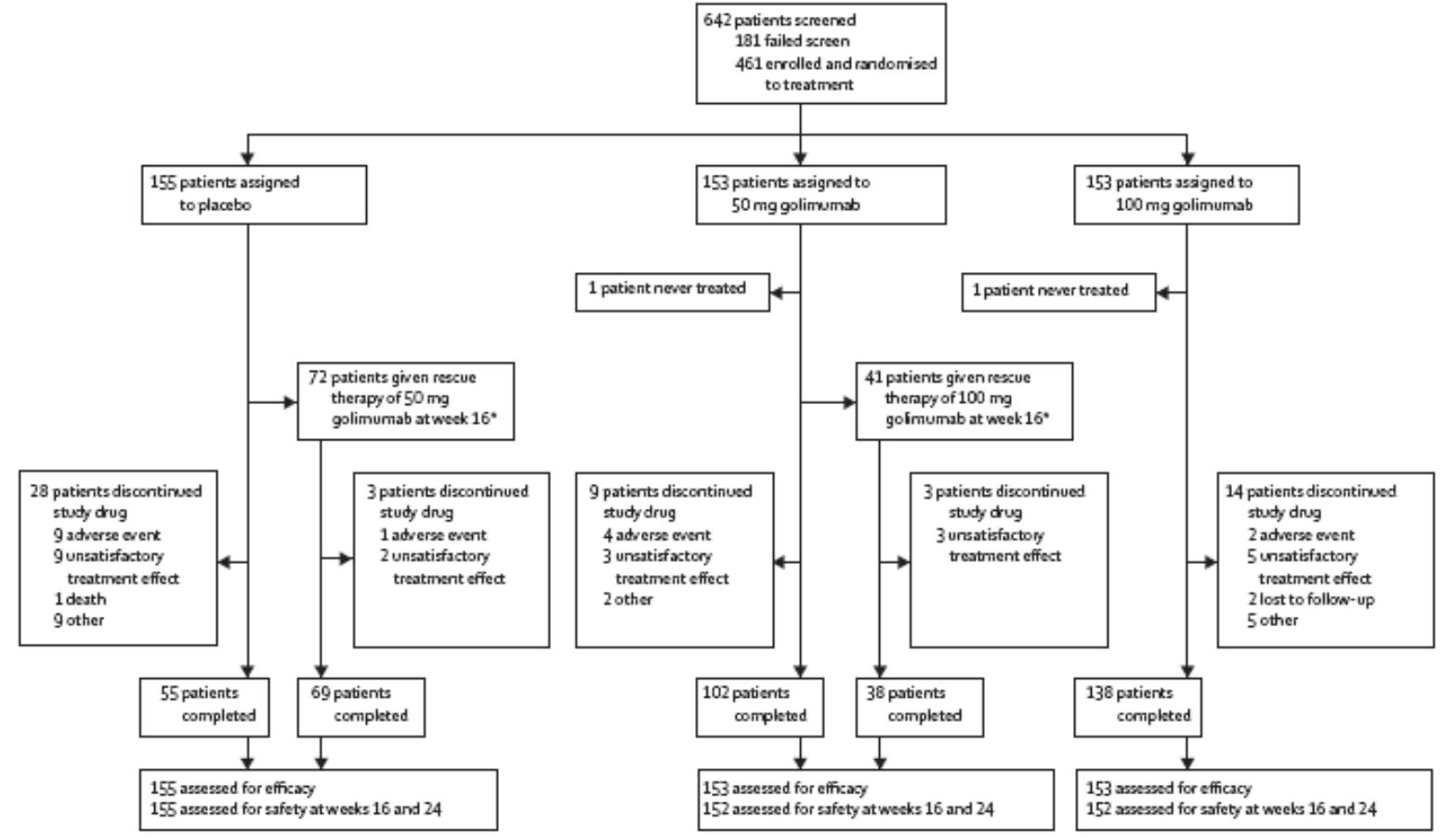

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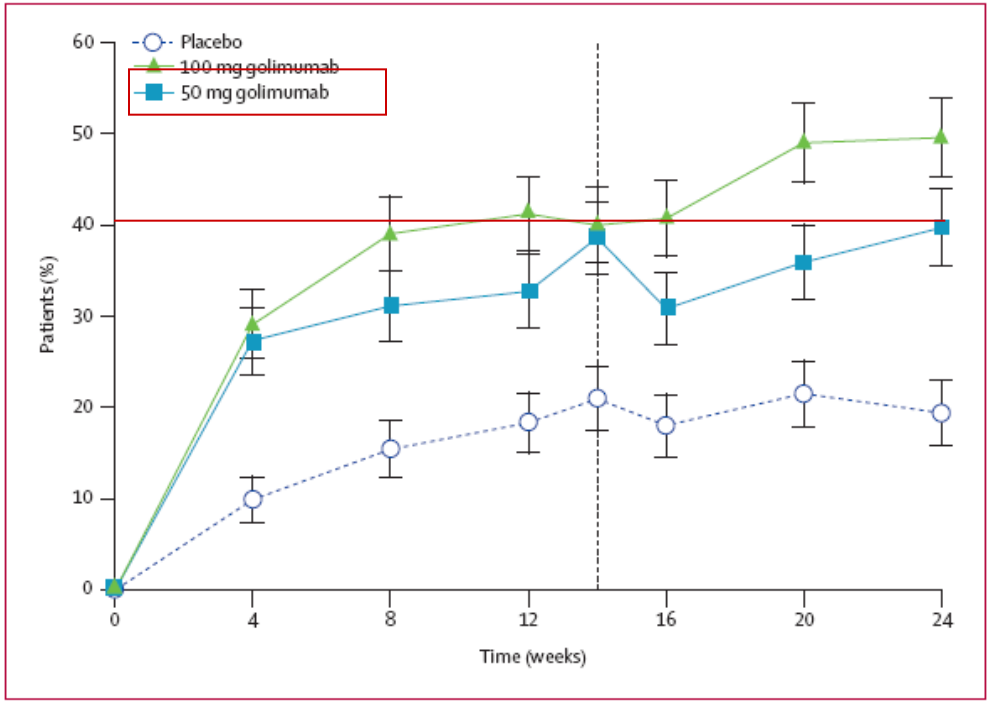
Ανταπόκριση ACR 20% στις 24 w



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	Placebo (n=155)		50 mg golimumab (n=153)			100 mg golimumab (n=153)			Combined golimumab groups (n=306)		
	Median (IQR)	Median change from baseline (IQR)	Median (IQR)	Median change from baseline (IQR)	p value	Median (IQR)	Median change from baseline (IQR)	p value	Median (IQR)	Median change from baseline (IQR)	p value
Week 14											
Swollen joint count (0–66)	12·0 (5·0 to 19·0)	−22·1% (−52·0 to 13·0)	7·0 (4·0 to 14·0)	−44·0% (−71·4 to −13·0)	0·0002	7·0 (2·0 to 14·0)	−50·0% (−77·8 to −10·5)	<0·0001	7·0 (3·0 to 14·0)	−50·0% (−75·0 to −12·5)	<0·0001
Tender joint count (0–68)	19·5 (12·0 to 32·0)	−6·2% (−50·0 to 18·8)	15·0 (7·0 to 32·0)	−34·1% (−66·7 to −11·1)	<0·0001	13·5 (5·0 to 30·0)	−41·1% (−74·2 to −7·6)	<0·0001	14·0 (6·0 to 32·0)	−36·4% (−71·8 to −8·1)	<0·0001
Patient assessment of pain (0–10 cm, VAS)	6·0 (3·9 to 7·8)	−9·9% (−34·1 to 15·4)	5·1 (2·5 to 7·2)	−26·0% (−57·3 to 0·0)	<0·0001	4·0 (2·1 to 6·0)	−38·1% (−64·6 to −4·5)	<0·0001	4·4 (2·3 to 6·7)	−30·9% (−62·1 to −3·2)	<0·0001
Patient global assessment of disease activity (0–10 cm, VAS)	6·0 (3·6 to 7·6)	−7·8% (−35·5 to 19·7)	5·1 (2·4 to 6·8)	−32·8% (−60·6 to 1·8)	<0·0001	4·1 (2·4 to 5·9)	−32·1% (−60·7 to −7·7)	<0·0001	4·5 (2·4 to 6·2)	−32·8% (−60·7 to 0·0)	<0·0001
Physician global assessment of disease activity (0–10 cm, VAS)	5·2 (3·3 to 10·0)	−10·1% (−38·3 to 17·9)	3·5 (1·7 to 5·6)	−38·9% (−71·0 to −8·5)	<0·0001	3·5 (1·4 to 5·5)	−47·1% (−70·4 to −12·1)	<0·0001	3·5 (1·6 to 5·5)	−42·6% (−71·0 to −10·0)	<0·0001
Assessment of physical function (0–3, HAQ-DI)	1·6 (1·1 to 2·1)	0% (−17·6 to 13·3)	1·4 (0·9 to 1·8)	−13·4% (−27·3 to 0·0)	0·0005	1·3 (0·6 to 1·8)	−17·6% (−43·8 to 0·0)	<0·0001	1·4 (0·8 to 1·8)	−14·9% (−33·3 to 0·0)	<0·0001
C-reactive protein concentration (mg/L)	9 (4 to 24)	0% (−25·8 to 33·3)	4 (3 to 11)	−33·3% (−64·3 to 0·0)	<0·0001	3 (3 to 9)	−24·4% (−63·6 to 0·0)	<0·0001	4 (3 to 10)	−25·0% (−64·3 to 0·0)	<0·0001
DAS28 score	5·8 (4·2 to 6·7)	−4·2% (−19·8 to 8·7)	4·9 (3·9 to 6·1)	−15·7% (−31·6 to −6·8)	<0·0001	4·7 (3·2 to 6·0)	−21·5% (−38·3 to −7·5)	<0·0001	4·7 (3·5 to 6·0)	−18·4% (−35·3 to −6·8)	<0·0001
FACIT-F score	27·0 (18·0 to 36·0)	1·0 (−4·0 to 8·0)	32·0 (19·0 to 38·0)	6·0 (−1·0 to 13·0)	0·0004	33·0 (23·0 to 42·0)	5·0 (−1·0 to 13·0)	0·0005	33·0 (21·0 to 40·0)	6·0 (−1·0 to 13·0)	<0·0001

Golimumab in patients with active rheumatoid arthritis after treatment with tumour necrosis factor α inhibitors (GO-AFTER study): a multicentre, randomised, double-blind, placebo-controlled, phase III trial

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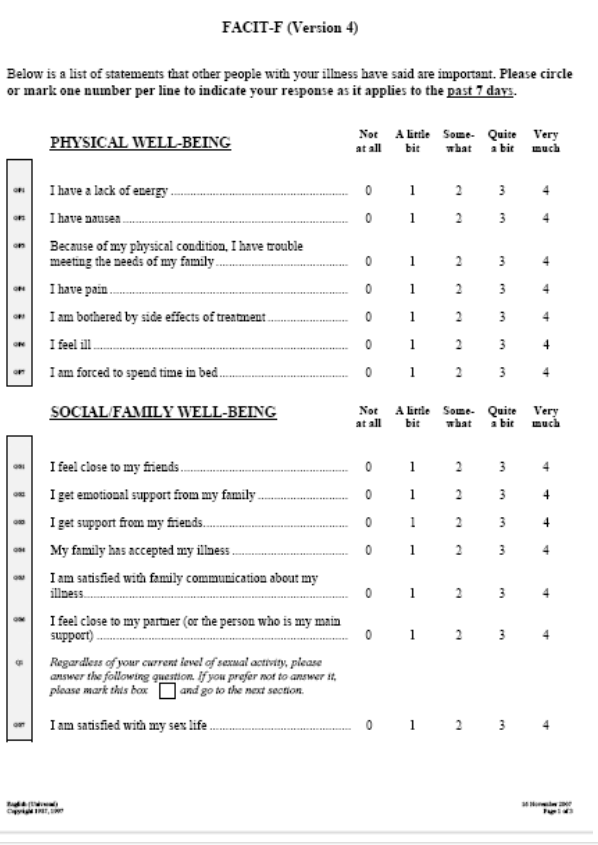
	Placebo (n=155)	50 mg golimumab (n=153)			100 mg golimumab (n=153)			Combined golimumab groups (n=306)		
		Patients (%)	Odds ratio (95% CI)	p value	Patients (%)	Odds ratio (95% CI)	p value	Patients (%)	Odds ratio (95% CI)	p value
Week 24										
Swollen joint count (0–66)	12·5 (7·0 to 20·0)	−3·1% (−50·0 to 30·0)	8·0 (3·0 to 16·0)	−40·0% (−80·0 to −4·0)	<0·0001	5·0 (1·0 to 10·0)	−60·0% (−87·9 to −33·3)	<0·0001	7·0 (2·0 to 12·0)	−53·8% (−85·7 to −15·4)	<0·0001
Tender joint count (0–68)	24·0 (14·0 to 41·0)	4·8% (−40·0 to 50·0)	15·0 (5·0 to 35·0)	−38·5% (−77·8 to 0·0)	<0·0001	11·0 (4·0 to 22·0)	−56·6% (−81·1 to −18·5)	<0·0001	13·0 (4·0 to 28·0)	−46·8% (−78·8 to −6·3)	<0·0001
Patient assessment of pain (0–10 cm, VAS)	6·5 (4·3 to 8·0)	−6·1% (−28·6 to 17·5)	5·2 (2·4 to 7·3)	−27·1% (−65·3 to −1·2)	<0·0001	4·4 (1·9 to 6·3)	−37·2% (−67·0 to −4·6)	<0·0001	4·7 (1·9 to 6·8)	−32·0% (−66·9 to −1·7)	<0·0001
Patient global assessment of disease activity (0–10 cm, VAS)	6·25 (4·0 to 7·9)	−4·5% (−34·9 to 27·8)	5·0 (2·2 to 7·2)	−24·3% (−64·7 to 1·3)	<0·0001	3·5 (1·9 to 6·1)	−35·6% (−67·2 to −4·3)	<0·0001	4·2 (2·0 to 6·4)	−32·6% (−66·9 to −1·7)	<0·0001
Physician global assessment of disease activity (0–10 cm, VAS)	5·6 (2·5 to 7·0)	−13·0% (−51·7 to 15·3)	3·3 (1·5 to 5·8)	−40·8% (−74·5 to −9·4)	<0·0001	2·7 (1·0 to 4·5)	−58·4% (−81·5 to −26·7)	<0·0001	2·9 (1·3 to 5·2)	−53·8% (−79·4 to −20·7)	<0·0001
Assessment of physical function (0–3, HAQ-DI)	1·5 (1·0 to 2·1)	0% (−25·0 to 17·6)	1·4 (0·8 to 1·8)	−13·3% (−33·3 to 0·0)	0·0003	1·1 (0·6 to 1·8)	−14·3% (−44·1 to 0·0)	<0·0001	1·3 (0·8 to 1·8)	−13·8% (−40·0 to 0·0)	<0·0001
C-reactive protein concentration (mg/L)	10 (5 to 26)	0% (−28·3 to 66·7)	6 (3 to 15)	−14·3% (−50·0 to 0·0)	<0·0001	3 (3 to 9)	−16·7% (−63·2 to 0·0)	<0·0001	4 (3 to 12)	−15·8% (−60·2 to 0·0)	<0·0001
DAS28 score	5·9 (4·0 to 6·9)	−1·6% (−17·8 to 14·8)	5·1 (3·0 to 6·1)	−18·6% (−36·0 to −2·6)	<0·0001	4·7 (3·0 to 5·4)	−25·8% (−40·5 to −12·2)	<0·0001	4·8 (3·0 to 5·8)	−22·0% (−39·2 to −5·6)	<0·0001
FACIT-F score	31·0 (22·5 to 40·0)	3·0 (−3·0 to 9·0)	31·0 (20·0 to 41·0)	5·0 (−1·0 to 12·0)	0·0211	33·0 (25·0 to 42·0)	6·0 (1·0 to 14·0)	0·0003	32·0 (22·0 to 42·0)	6·0 (0·0 to 13·0)	0·0008

FACIT F



FACIT-F (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

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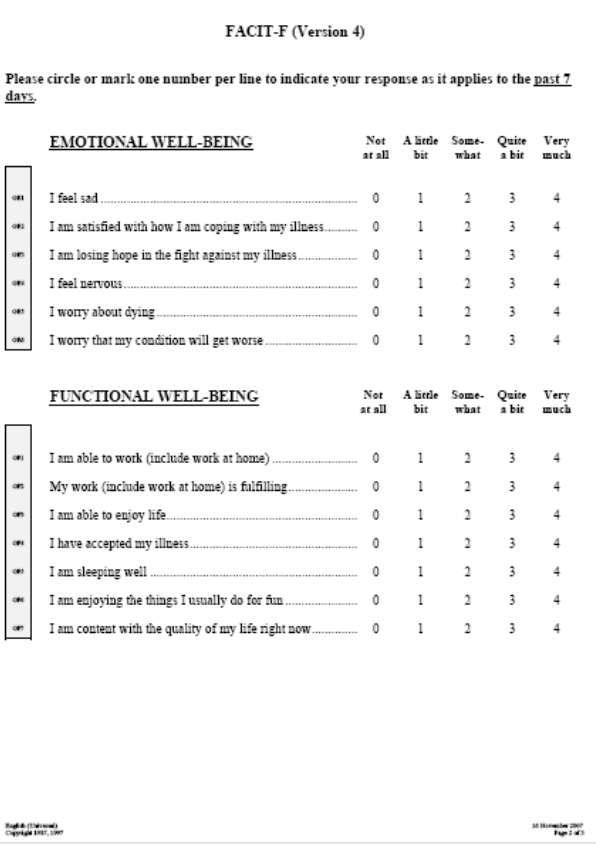

FACIT-F (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

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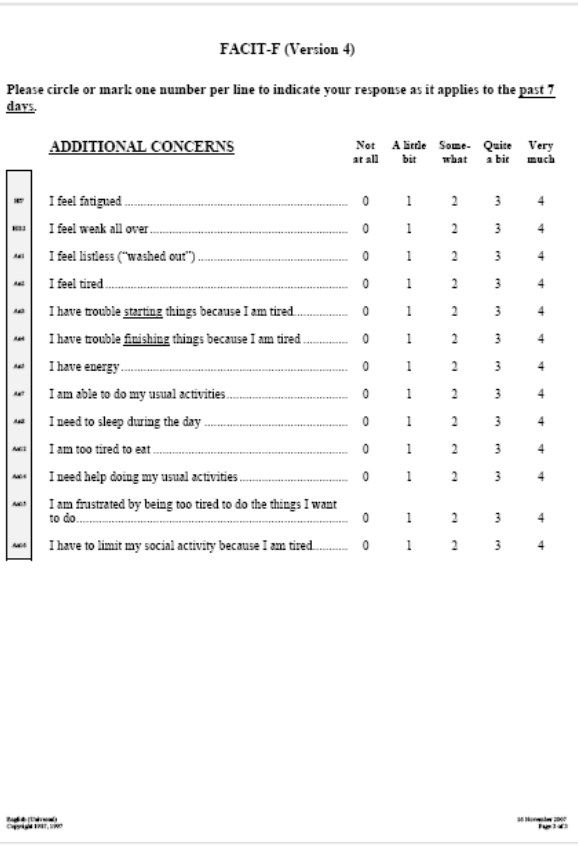

FACIT-F (Version 4)

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
BF7	I feel fatigued	0	1	2	3	4
BFS2	I feel weak all over	0	1	2	3	4
AA1	I feel listless ("washed out")	0	1	2	3	4
AA2	I feel tired	0	1	2	3	4
AA3	I have trouble starting things because I am tired	0	1	2	3	4
AA4	I have trouble finishing things because I am tired	0	1	2	3	4
AA5	I have energy	0	1	2	3	4
AA7	I am able to do my usual activities	0	1	2	3	4
AA8	I need to sleep during the day	0	1	2	3	4
AAC1	I am too tired to eat	0	1	2	3	4
AAC4	I need help doing my usual activities	0	1	2	3	4
AAC7	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
AAC8	I have to limit my social activity because I am tired	0	1	2	3	4

English (Universal)
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http://www.facit.org/FACITOrg/Questionnaires

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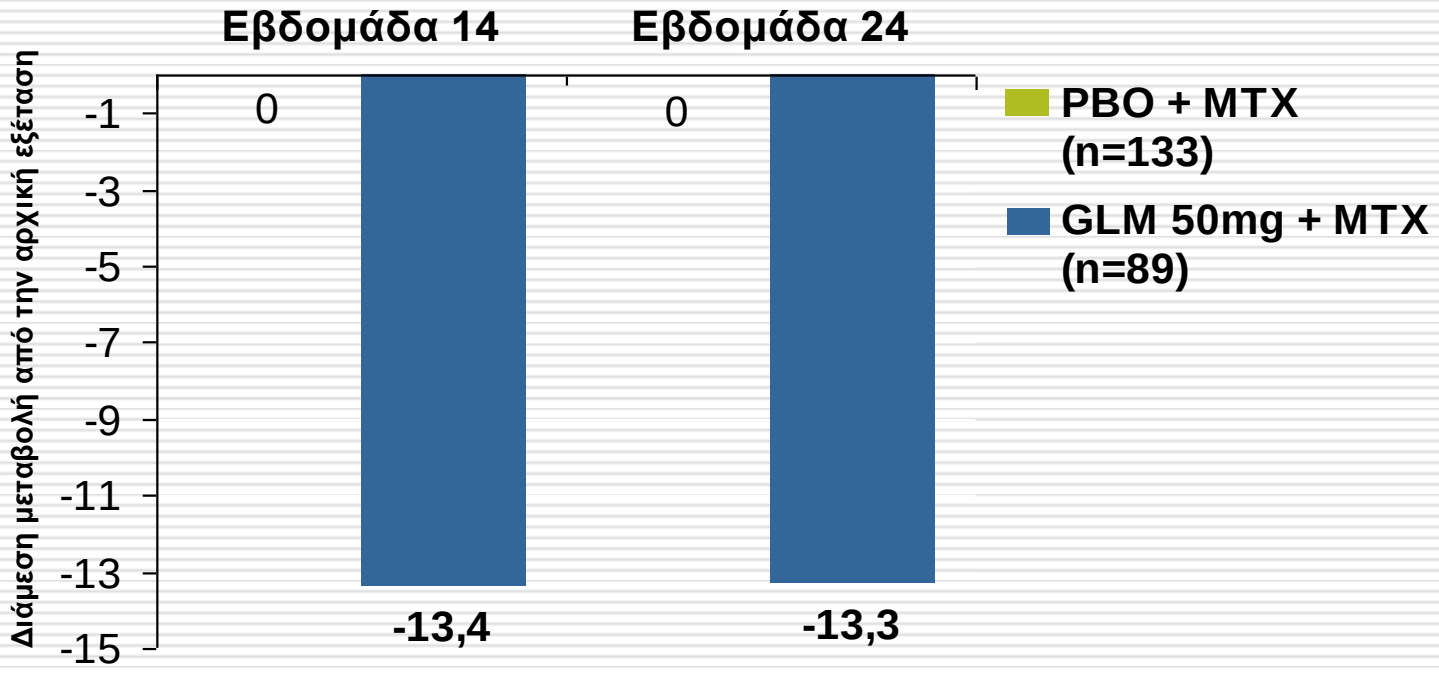
Διάμεση μεταβολή του HAQ στις 14 & 24 w



Smolen J *et al.*, 2009 The Lancet, 374:210-221

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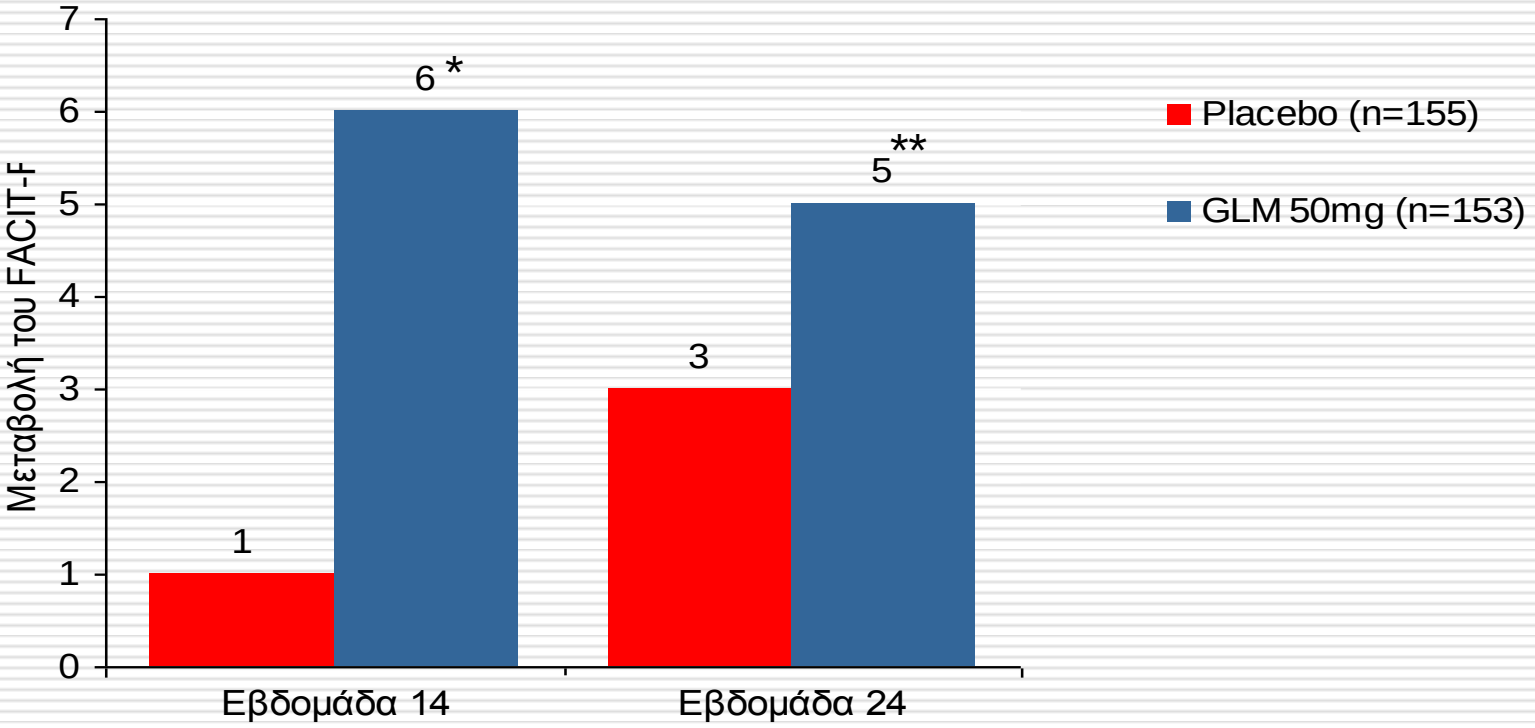
Δευτερεύον τελικό σημείο: Βελτίωση του FACIT-F

Μεταβολή του FACIT-F τις εβδομάδες 14 και 24



* $p<0.0003$; ** $p<0.05$ vs placebo

Smolen J *et al.*, 2009 The Lancet, 374:210-221.

GOLIMUMAB IN RHEUMATOID ARTHRITIS PATIENTS PREVIOUSLY TREATED WITH ANTI-TNF ALPHA AGENTS: 2 YEAR RESULTS FROM GO-AFTER STUDY

Assessment	Group 1*	Group 2*	Group 3*
Randomized pts (n):	150	147	148
Pts who entered EE at Wk 16	70(46.7%)	41(28.1%)	-
Pts who were receiving GLM 50 mg at Wk 24	120	96	-
Pts who had an opportunity to receive a dose escalation after DBL	107(89.2%)	78(81.3%)	-
Pts who received a dose escalation at anytime through Wk 100	78(72.9%)	41(52.6%)	-
ACR 20			
Wk 52	58(38.7%)	59(40.1%)	77(52.0%)
Wk 100	57(38.0%)	64(43.5%)	66(44.6%)
ACR 50			
Wk 100	73(48.7%)/34(22.7%)	81(55.1%)/34(23.1%)	88(59.5%)/41(27.7%)
No of pts who achieved HAQ improvement ≥0.25 at wk24 and maintained improvement through wk100	35/45(77.8%)	55/68(80.9%)	55/73(75.3%)
No. swollen joints at Wk 100 % improvement from baseline	60.0 (10.00, 86.36)	64.52 (25.00, 86.36)	71.13 (28.57, 95.45)

81% των ασθενών σε GLM 50 mg που πέτυχαν βελτίωση HAQ>0.25 την εβδομάδα 24, τη διατήρησαν ως την εβδομάδα 100

J.S. Smolen et al, Ann Rheum Dis 2010;69(Suppl3):681

GOLIMUMAB ADMINISTERED SUBCUTANEOUSLY EVERY FOUR WEEKS IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS WHO WERE PREVIOUSLY TREATED WITH ANTI-TNFA AGENT(S): EFFICACY RESULTS OF THE RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, GO-AFTER STUDY THROUGH WEEK 160

No. of randomized pts[1]	**Group 1** (Placebo→ 50/100 mg)[2] N=150	**Group 2** (50/100 mg)[3] N=147	**Group 3** (100 mg) N=148
Baseline (mean ± SD)			
Disease duration (years)	12.4 ± 9.58	12.4 ± 9.24	10.6 ± 7.90
CRP (mg/dL)	2.1 ± 3.16	2.2 ± 2.97	2.1 ± 3.38
HAQ score (0-3)	1.6 ± 0.6	1.6 ± 0.7	1.5 ± 0.7
DAS28-CRP score	5.7 ±1.05	5.9 ± 1.11	5.7 ± 0.98
Number (%) of pts			
ACR 20 response			
Wk52	58/150 (38.7%)	59/147 (40.1%)	77/148 (52.0%)
Wk100	57/150 (38.0%)	64/147 (43.5%)	66/148 (44.6%)
Wk160	47/75 (72.7%)	54/81 (66.7%)	46/81 (56.8%)
ACR 50 response			
Wk52	32/150 (21.3%)	27/147 (18.4%)	35/148 (23.6%)
Wk100	36/150 (24.0%)	36/147 (24.5%)	37/148 (25.0%)
Wk160	25/75 (33.3%)	36/81 (44.4%)	29/81 (35.8%)
DAS28-CRP response			
Wk52	76/150 (50.7%)	84/147 (57.1%)	98/148 (66.2%)
Wk100	73/150 (48.7%)	81/147 (55.1%)	88/148 (59.5%)
Wk160	54/75 (77.1%)	66/81 (82.5%)	61/81 (79.2%)
HAQ improvement ≥ 0.25			
Wk52	58/108 (53.7%)	65/116 (56.0%)	74/116 (63.8%)
Wk100	51/92 (55.4%)	59/97 (60.8%)	62/104 (59.6%)
Wk160	44/75 (58.7%)	53/81 (65.4%)	51/80 (63.8%)

[1]Excludes 16pts (5/Grp1, 6/Grp2, 5/Grp3) from site7465 due to study conduct violations. [2]Includes pts who early escaped at wk16 or crossed over at wk24 to receive GLM50mg or dose escalated after the wk24 database lock to receive GLM 100mg. [3]Includes pts who early escaped at wk16 or dose escalated after the wk24 database lock to receive GLM100mg.

Smolen et al
AB0425

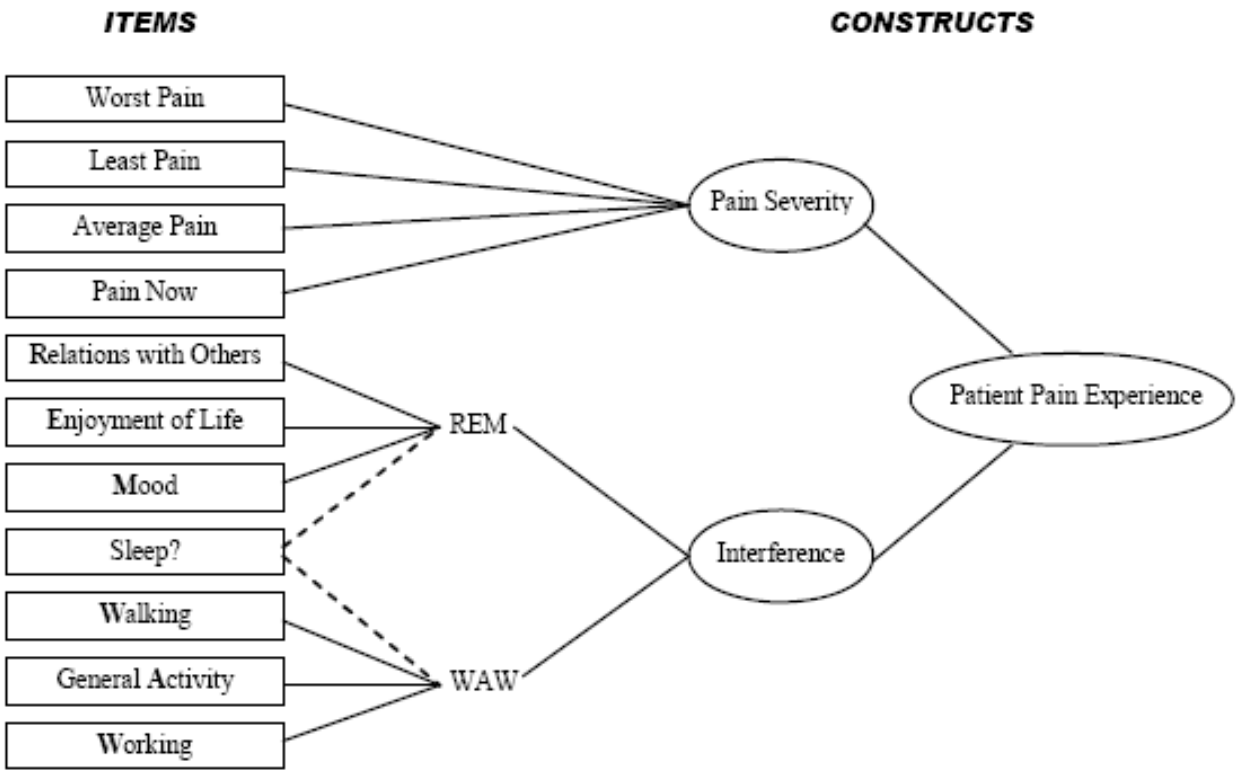
Treat-To-Target for the Management of Rheumatoid Arthritis: A Validation Using Patient Reported Outcomes Data from Two Phase III Clinical Trials of Golimumab

- The overall distribution of SF36-PCS shifted significantly towards a distribution observed in the normal population at week 24 through 104

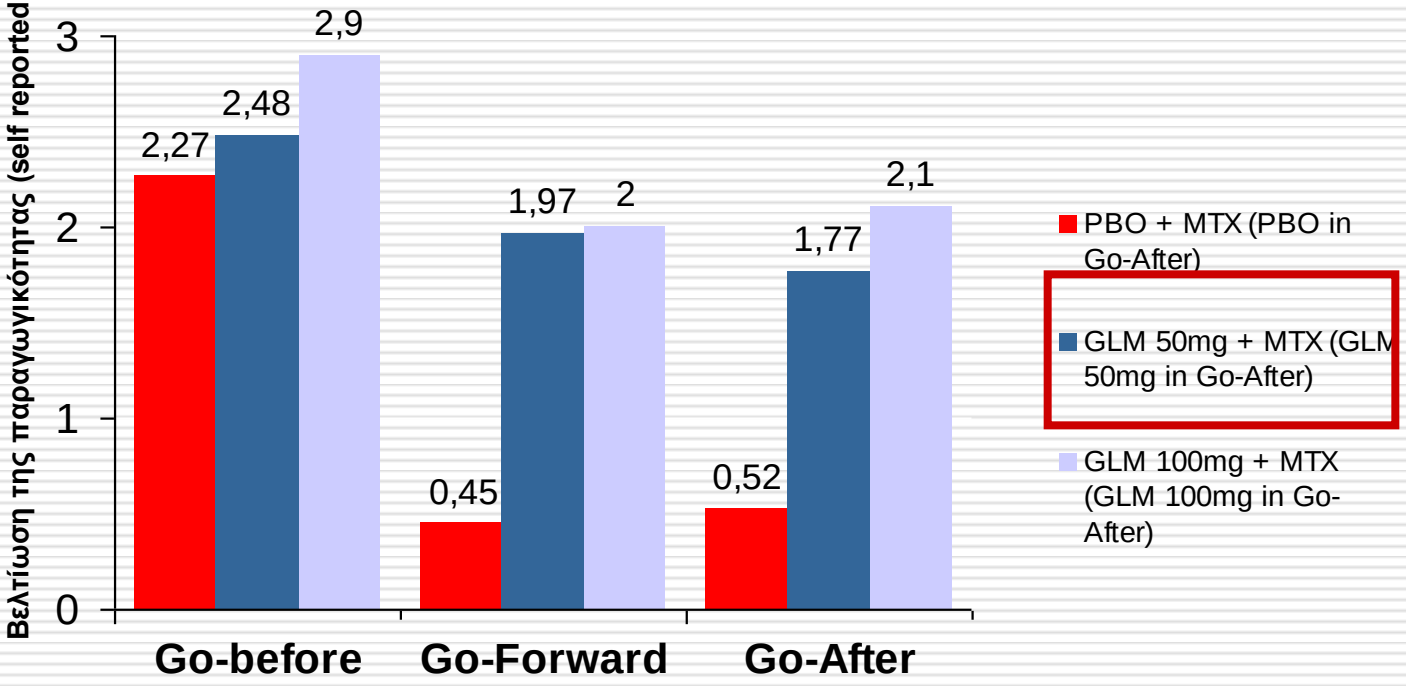
- Compared to patients without remission, more **patients in remission** at week 24 achieved
  - a normal physical function (HAQ < 0.5) (75.3% vs. 27.3%),
  - a SF-36 PCS>50 (median value of general population) (48.3%, vs. 7.6%) and
  - a SF-36 MCS>50 (median value of general population) (66.3% vs. 40.3%),
  - regained employability (43.5% vs. 27.6%)
  - achieved significant improvement in work productivity (80% vs. 28.3%) from baseline (all p-values<0.01).

- Greater improvements (median) in FACIT-Fatigue (week 24: 12.0 vs. 4.0) and in BPI-Pain score (week 14: 2.1 vs. 0.8) were observed among patients in remission than patients without remission

The **Brief Pain Inventory** (BPI)



Το Golimumab αυξάνει σημαντικά την **παραγωγικότητα** ασθενών με PA (3 μελέτες)



J. Buchanan, R. Fleischmann et al, EULAR 2009, abstr. THU0210

GENDER DIFFERENCES IN BASELINE DISEASE CHARACTERISTICS, CLINICAL EFFICACY, AND SAFETY IN RHEUMATOID ARTHRITIS PATIENTS FROM THREE RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDIES OF GOLIMUMAB

	Men	Women
Pts treated	289	1253
Baseline characteristics (mean/median)		
Age (yrs)	53.4/54.0	50.6/51.0**
CRP (mg/dL)	2.4/1.1	2.1/1.0
DAS-28	5.8/6.0	6.3/6.3**
Disease duration (yrs)	6.6/3.5	7.6/4.6*
ESR (mm/hr)	35.9/30.0	42.0/36.0**
HAQ score	1.2/1.1	1.6/1.6**
Morning stiffness (min)	143.6/90.0	159.8/90.0
Rheumatoid factor	222.0/87.0	180.3/65.0
Swollen joint count	15.4/12.0	15.9/13.0
Tender joint count	24.6/20.0	28.5/26.0**
Anti-CCP positive	76.6%	74.5%
Clinical Efficacy @ Wk24 (% or mean/median improvement)		
ACR20/50/70	50%/34%/20%	44%/24%**/12%**
DAS28(CRP) response/ remission	62%/34%	59%/24%**
Change in CRP	-1.2/-0.4	-0.8/-0.2*
PROs @ Wk24 (mean/median improvement)		
SF-36 PCS (2 trials)	7.9/7.0	7.2/6.0
SF-36 MCS (2 trials)	2.6/2.1	4.2/3.5
FACIT-fatigue (2 trials)	5.1/4.0	5.5/5.0
HAQ	0.4/0.3	0.4/0.4
Safety @ Wk24 (%)		
Adverse events	69.6%	75.4%**
Serious adverse events	6.2%	7.1%
Serious infections	2.4%	2.5%

*, ** p<0.05, 0.001, respectively, versus men.

DE Frust et al . Ann Rheum Dis 2010;69(Suppl3):681

Golimumab, a Human Anti-TNF_ Monoclonal Antibody Administered Subcutaneously Every Four Weeks as Monotherapy in Patients with Active Rheumatoid Arthritis Despite DMARD Therapy: 24-Week Results of Clinical and Radiographic Assessments

ACR/ARHP 10 Scientific Meeting
Atlanta
Pre-Conference Courses: November 6-7, 2010
Annual Scientific Sessions: November 7-11, 2010

Tables. Efficacy at Wk 14 and Wk 24

Assessment	PBO	GLM 50 mg	GLM 100 mg
Patients treated (n)	105	101	102
Primary Endpoint			
ACR 20 at Wk 14	20 (19.0)	51 (50.5)*	60 (58.8%)*
Secondary Endpoints			
Wk 14			
ACR 50	6 (5.7%)	29 (28.7%)*	33 (32.4%)*
ACR 70	1 (1.0%)	13 (12.9%)**	12 (11.8%)***
DAS28 (ESR) moderate responders	26 (27.7%)	69 (71.1%)*	74 (74.0%)*
Improvement from baseline in HAQ (mean [SD]), range	−0.042 (0.546) (−1.88, 1.75)	0.255 (0.507)* (−1.88, 1.38)	0.330 (0.450)* (−0.750, 1.75)
Wk 24			
Change from baseline in vdH-S (TSS)			
Mean (SD), (range)	2.58 (4.69) (−2.5, 29.8)	1.87 (4.09) (−1.8, 23.0)	2.13 (10.42) (−2.5, 102.5)
Median (IQ range)	1.00 (0.00, 3.50)	0.50 (0.00, 2.00)	0.00 (−0.50, 2.00)
p-value		0.1802	0.0043
Change from baseline in joint space narrowing score			
Mean (SD), (range)	0.90 (1.89) (−1.0, 9.5)	1.02 (2.83) (−1.5, 17.5)	0.96 (5.05) (−2.0, 48.5)
Median (IQ range)	0.00 (0.00, 1.00)	0.00 (0.00, 0.50)	0.00 (0.00, 0.50)
p-value		0.3373	0.0832
Change from baseline in bone erosion score			
Mean (SD), (range)	1.28 (2.49) (−2.5, 14.5)	0.98 (2.06) (−1.5, 11.5)	1.13 (5.69) (−2.5, 54.0)
Median (IQ range)	0.50 (0.00, 2.00)	0.50 (0.00, 1.00)	0.00 (0.00, 1.00)
p-value		0.5895	0.0316

*p<0.0001; **p=0.0007; ***p=0.0013

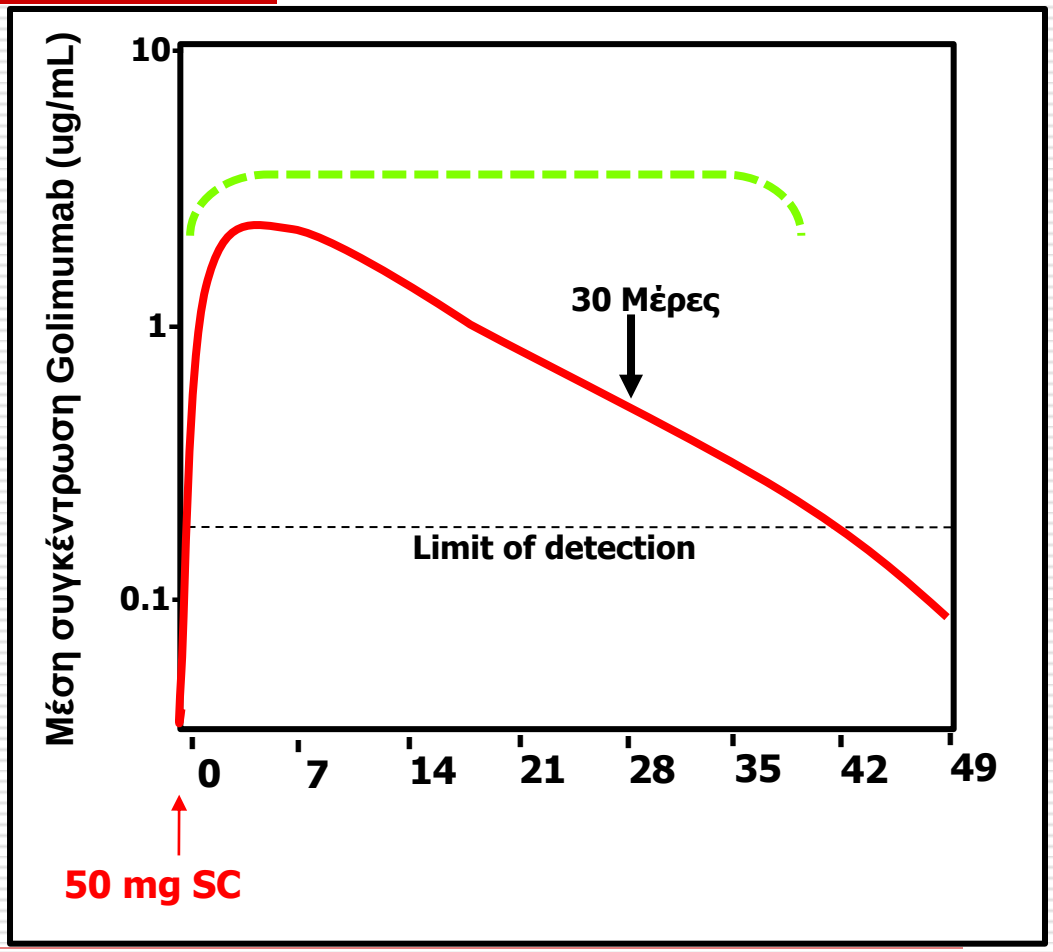
Tsutomu Takeuchi et al , 1814

Golimumab

κλινική μελέτη: Μηνιαία χορήγηση

Lack of Racial Differences in the Pharmacokinetics of Subcutaneous Golimumab in Healthy Japanese and Caucasian Male Subjects

Jie Ling, PhD, Sally Lyn, MSc, Zhenhua Xu, PhD, FCP, Meguru Achira, PhD, Esther Bouman-Thio, MD, Akira Shishido, MSc, Joyce Ford, BS, Gopi Shankar, PhD, MBA, Carrie Wagner, PhD, Kenneth T. Kim, MD, Hugh M. Davis, PhD, and Honghui Zhou, PhD, FCP



J Clin Pharmacol 2010;50:792-802

συμπεράσματα

- Ο ασθενής με PA ενδιαφέρεται για την ποιότητα ζωής
- Και η βελτίωση της ποιότητας ζωής , που η θεραπευτική αγωγή προσφέρει, πρέπει να αποδεικνύεται
- Το golimumab (πλήρως ανθρώπινο anti TNF –α μονοκλωνικό αντίσωμα) είναι αποτελεσματικό & ασφαλές στην αντιμετώπιση της PA
- Μέσα από σειρά μελετών & μηνιαία χορήγηση & πένα
  - φαίνεται ότι προσφέρει σημαντική βελτίωση στην ποιότητα ζωής των ασθενών με RA

Είναι δεδομένο …!

ευχαριστώ !