



Improvement in Quality of Life of Rheumatoid Arthritis Patients on Biologic Therapy

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Cost of Biologic Therapy

- Total world market for anti-TNF inhibitors in RA in 2007 was approx. €7 billion
- While 90% of patients are treated with conventional disease modifying antirheumatic drugs (DMARDs), 90% of the cost is attributed to biologics
- In Ireland the spend on RA has increased dramatically in the last 5 years and this is mainly related to drug therapy and specifically the newer biologic disease modifying agents

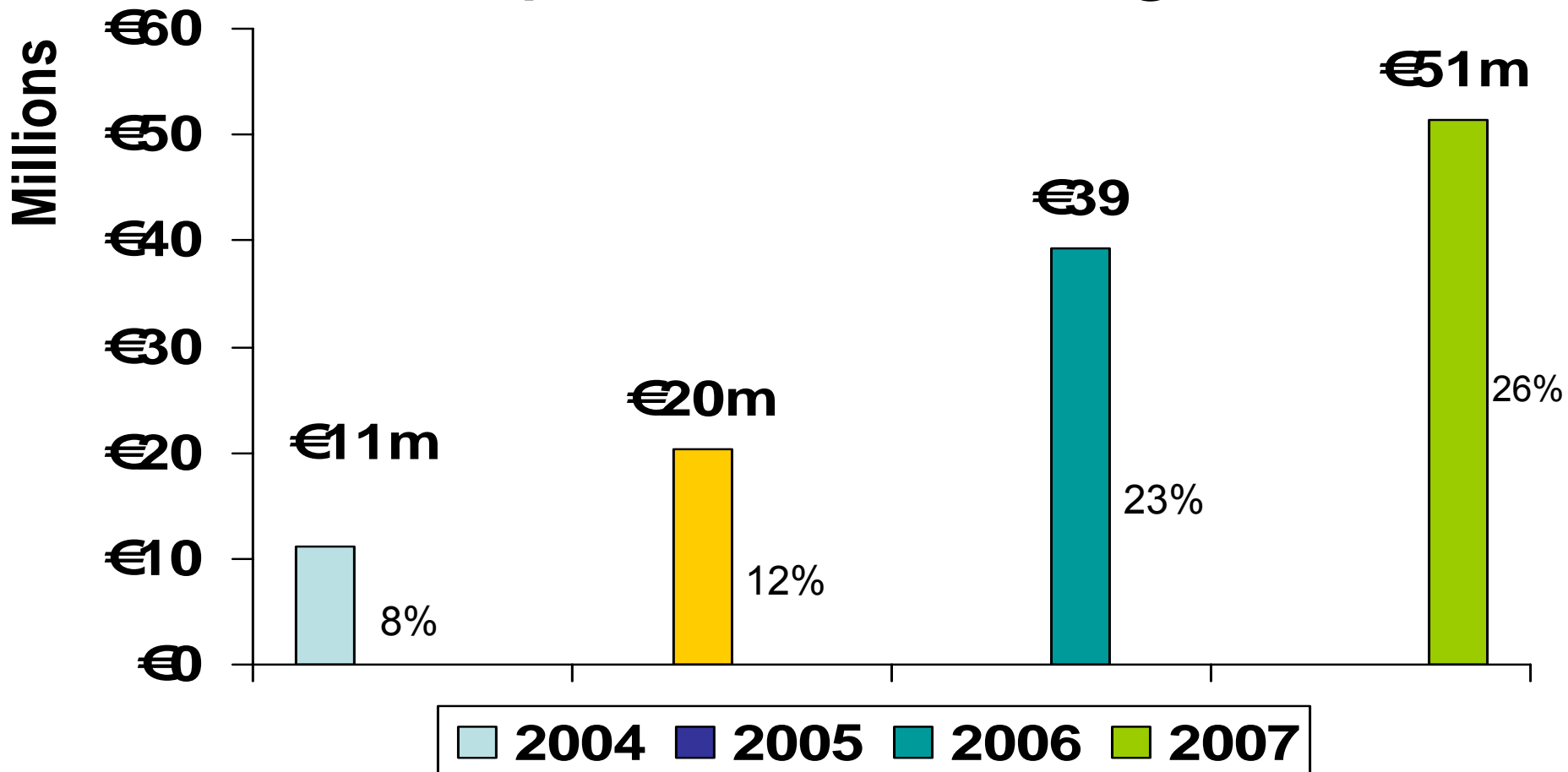
Biologic Drugs

- There are currently six main biologic drugs licensed for RA in Ireland:
 - Adalimumab (Humira®), etanercept (Enbrel®), infliximab (Remicade®), anakinra (Kineret®), rituximab (Mabthera®) and abatacept (Orencia®)
- Self Injectable (i.e. Humira®, Enbrel® and Kineret®) are currently reimbursed under the high technology drugs scheme in Ireland
- Remicade®, Mabthera® and Orencia® can only be prescribed in hospital

Biologic Drugs

- Three main modes of action:
 - Anti-Tumour Necrosis Factor (TNF) (Humira®, Enbrel®, Remicade®)
 - B cell target (Mabthera®)
 - T cell targeted (Orencia®)
- Consistently been shown to reduce disease activity to a greater extent in RA patients than conventional DMARDs
- The focus of this project is on the anti-TNF currently approved in RA

Irish Spend on Biologics



Rheumatoid Arthritis

Recent Onset Disease



Moderately Advanced



Severely Advanced



Disease Activity Measurement

- DAS 28 – based on joint score(28), laboratory measure of inflammation (ESR or CRP) and global health measurement as measured by patient
- High Disease Activity - > 5.1
- Moderate - >3.2 and ≤ 5.1
- Good - ≤ 3.2
- Remission - <2.6

- Does a Good DAS 28 = Good QoL?
- Quality-of-life (QoL) assessments are particularly important in the absence of a cure for RA.



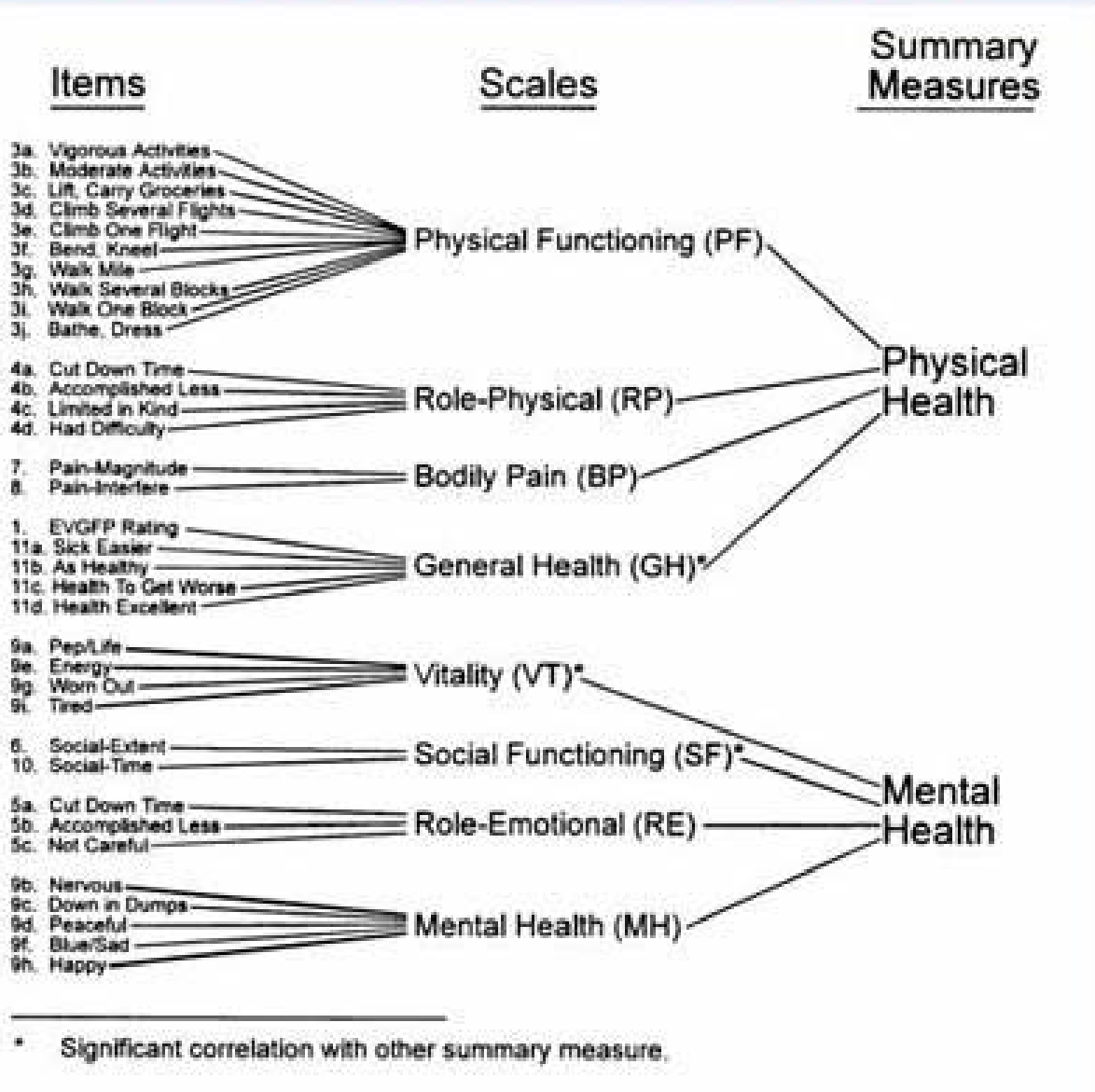
Patient Reported Outcomes (PROs)

- PRO's are increasingly used as outcome measures in RCTs
- OMERACT have recognised PROs as important measures in determining improvement
- May be more sensitive to change than disease activity scores

Generic vs. Disease Specific HRQoL Measures

- Generic - SF-36, EQ-5D, HUI
- Disease specific e.g. RA (RAQoL), musculoskeletal disease (HAQ)
- Generic measures allow for outcome comparison but may not be as sensitive to change as disease specific measures

SF-36[®] Measurement Model



Methodology

- Prospective review of patients on biologic agents attending a rheumatology biologic clinic
- All patients entered onto a database between 2004 and 2007 with rheumatoid arthritis included (N=241)
- Completed SF-36 (version 1) at baseline and 1 year post initiation of biologic therapy (self-administered)
- DAS 28 was also completed at these time points

Demographics (N=241)

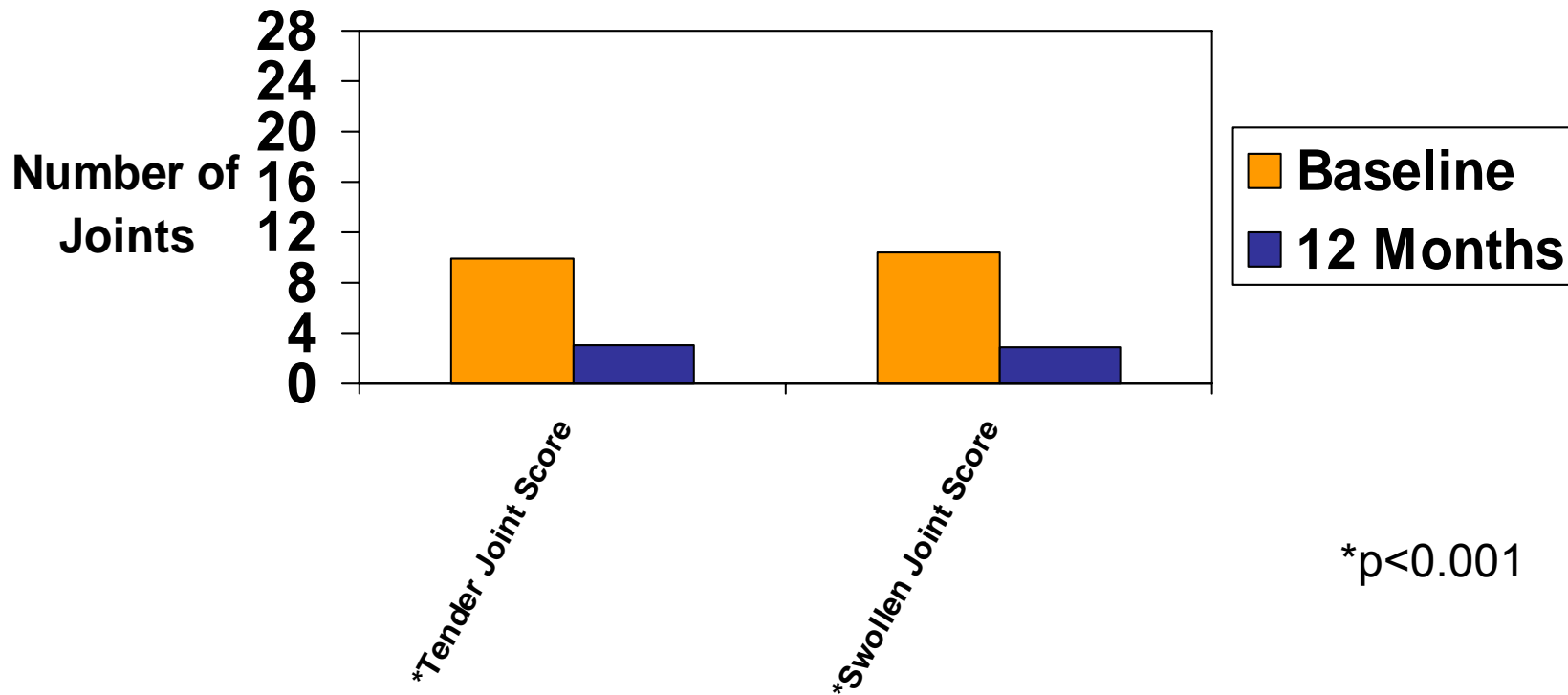
Mean Age	56 years (17-85yrs)
Female (%)	70%
Mean RA Duration	14 years (1-42yrs)
Mean DAS 28 (Baseline)	5.6 (SD 1.1)
Mean DAS 28 (12mths)	2.8 (SD 1.1)



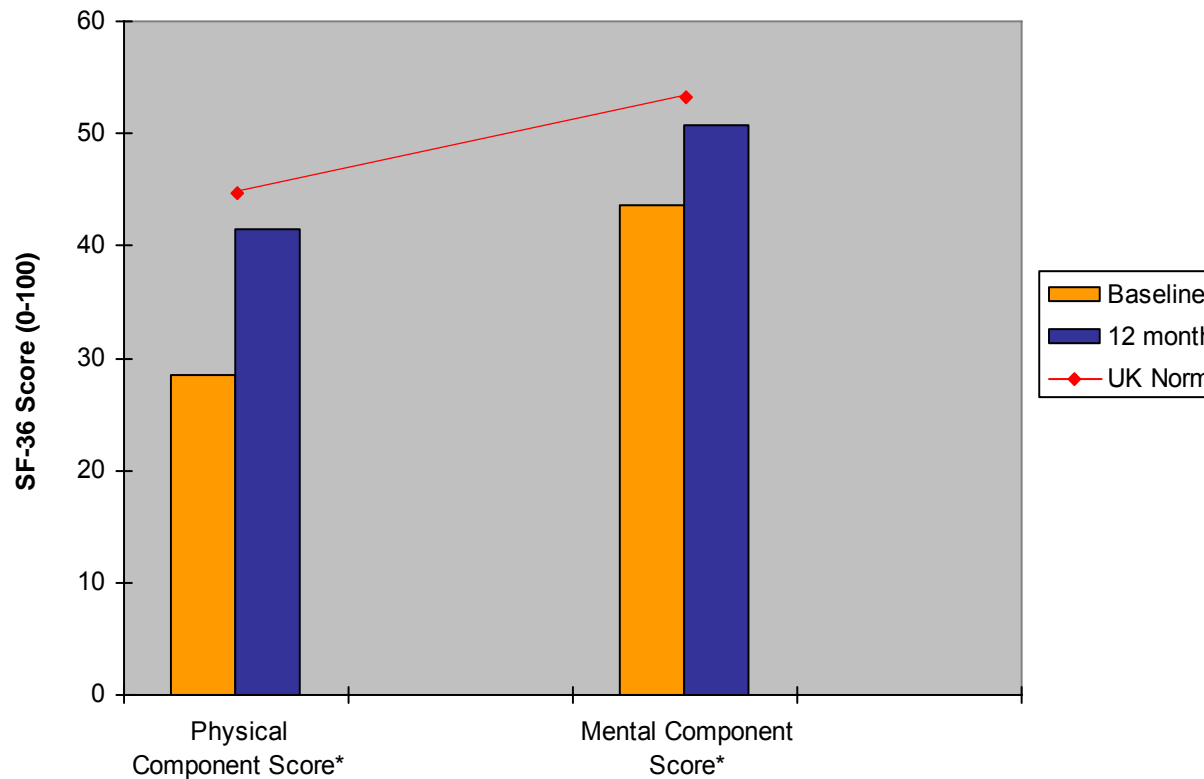
DMARD History

- 94% of patients had previously been on a DMARD
- 82% had previously been on methotrexate
- At baseline 72% were on DMARD - 84% were on methotrexate
- At 12 months 81% were on DMARDs concurrently with biologic

Mean Tender and Swollen Joint Scores Pre and Post Biologic Therapy (N=89)

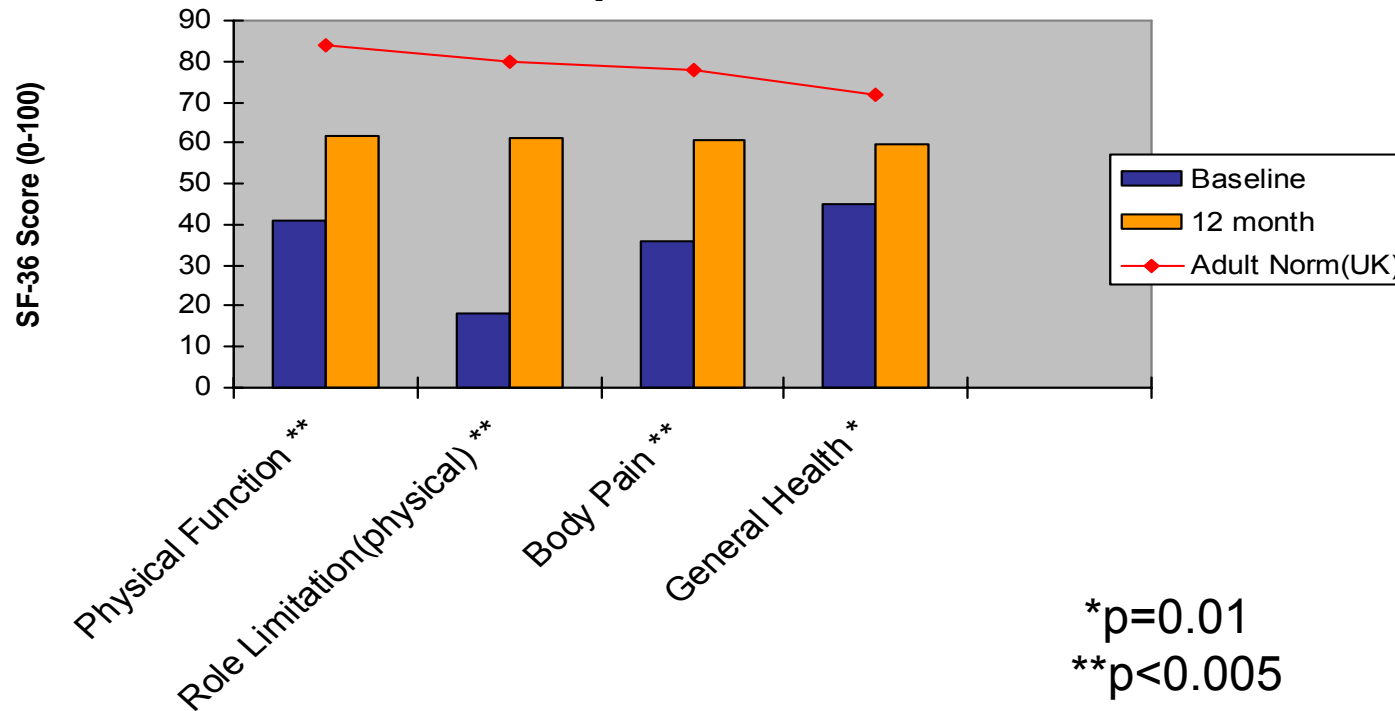


Mean Physical and Mental Component Scores Pre and Post Biologic Therapy

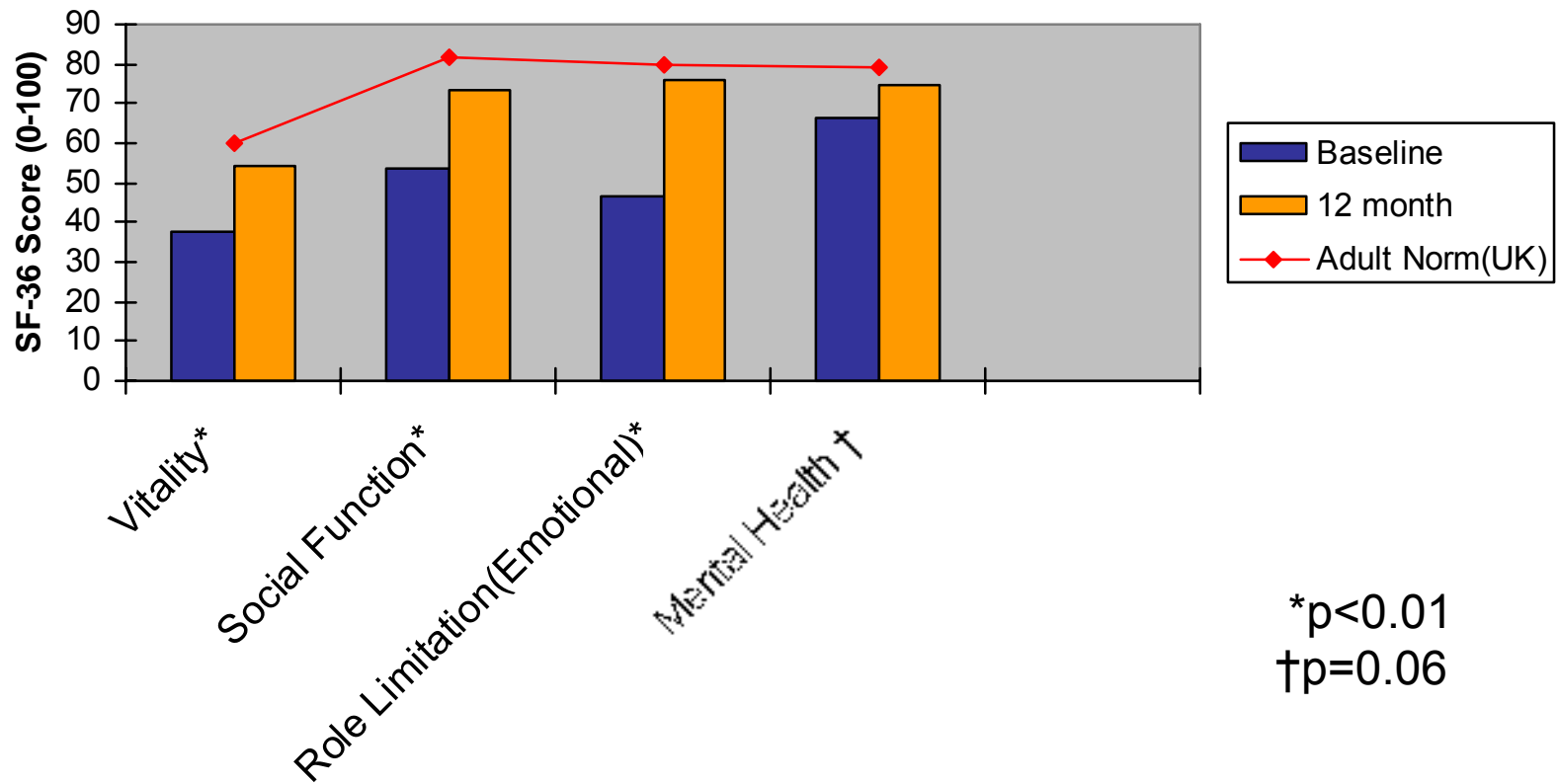


*p<0.05

Change in Scales associated with Physical Component Score



Change in Scales associated with Mental Component Score



*p<0.01
†p=0.06

Relationship between HRQoL and Disease Activity Score

- There was a significant negative correlation identified between the change in DAS 28 scores and the change in PCS ($r = -0.445$, $p < 0.001$).
- A significant correlation was not seen with DAS 28 and MCS ($r = -0.114$, $p = 0.366$)

Summary

- There is a dramatic increase in QoL of patients with RA following 1 year of biologic therapy
- QoL as demonstrated by PRO approaches UK norms post biologic therapy
- These results are consistent with other studies examining the effect of biologic therapy on QoL (Han C et al., 2007)

Future Aims

- Continue to collect data on this patient cohort alongside cost data
- Use the SF-6D to convert these SF-36 scores into utilities
- To examine the relationship between the DAS28 and these utilities



Thank You

- Patients in the rheumatology Unit
- The specialist nurses in the unit Miriam Molloy, Alexia Grier and Catherine Slattery
- My colleagues in the NCPE, Dublin