What is DANBIO?

DANBIO is a nationwide registry, approved as a clinical quality registry by the Danish National Board of Health in 2006. All adult, rheumatologic patients treated with biological drugs, e.g. tumor-necrosis-alpha (TNF-alpha) inhibitors are to be recorded in the registry. In addition, all patients with rheumatoid arthritis are to be registered, regardless of their treatment. The approval by the Danish National Board of Health implies that the registration of these groups of patients in DANBIO is mandatory for all departments and that patient consent to the registration is not required.

In 2015, 24 departments of rheumatology have been reporting to the registry. This number comprises all Danish departments of rheumatology treating patients with chronic rheumatoid arthritis. Furthermore, a total of 35 private rheumatology clinics have been given access to record their patients in DANBIO. In 2015, 18 of these clinics have been reporting actively to the registry.

The aim of DANBIO is to collect information on patients with rheumatoid arthritis as well as all the patients treated with biologicals. The data is being used to ensure efficient treatment of the individual patient, and is furthermore an important asset in scientific studies.

The registry was founded in 2000 as the result of a joint effort between the Danish Society of Rheumatology and the Danish Institute for Rational Pharmacotherapy.

The registry is run by a steering committee. The daily administration is handled in the DANBIO general office, situated at the Glostup Hospital. The general office is staffed by a Head of Secretariat as well as a secretary.

The registry has been reported to and approved by the Danish Data Protection Agency (reference number 2012-58-0023).

Funding

The Danish Regions' funding pool for clinical quality registries has donated an operational grant for 2014 of 476.073 DKK.

Additionally, the DANBIO development and research activities are financed by sponsorships approved by the legal department of the Capital Region of Denmark, the Danish Society of Rheumatology and the Danish Institute for Rational Pharmacotherapy. The following companies have been sponsors in 2015: AbbVie A/S, Bristol Myers Squibb A/S, Hospira Nordic AB, MSD Danmark ApS, Roche A/S, Pfizer Inc., UCB Nordic A/S.

The sponsors have no influence on registry activities, data collection, analysis or publications and have no access to the registry. The sponsors receive data on adverse events etc., but only in a depersonalised form so that no data can be traced back to a person or a department.

Steering committee

In 2015 the DANBIO steering committee comprised the following members:

Consultant in Rheumatology, Professor, MD, PhD
Merete Lund Hetland
(Chairman)

Consultant in Rheumatology, MD
Gina Kollerup
Appointed by the Danish Society of Rheumatology for the Capital Region of Denmark

Consultant in Rheumatology, MD, PhD
Hanne Merete Lindegaard
Appointed by the Danish Society of Rheumatology for the Southern Denmark Region

Consultant in Rheumatology, MD
Mette Yde
Appointed by the Danish Society of Rheumatology for the Central Denmark Region

Consultant in Rheumatology, MD, PhD
Mette Holland-Fischer
Appointed by the Danish Society of Rheumatology for the North Denmark Region

Consultant in Rheumatology, MD, PhD
Randi Pelck
Appointed by the Danish Society of Rheumatology for Region Sealand

MD, PhD student
Anton Wulf Christensen
Appointed by Junior Rheumatologists, Denmark[1]

Chief Consultant
Monika Madsen
The Capital Region of Denmark (the registry host region) and Centre of Competence for Nationwide Clinical Registries (KCØ[2])

Consultant in Rheumatology, MD
Dorte Vendelbo Jensen
Head of Secretariat in DANBIO, participating in the steering committee meetings without voting rights

Registry history

The first biological drugs, the so-called TNF-alpha inhibitors, were put on the market around year 2000. Based on the high treatment price and promising results in clinical studies of the drugs the

[1] Yngre Reumatologer

[2] Kompetencecenter for Landsdækkende Kliniske Databaser

Danish Institute for Rational Pharmacotherapy represented by Consultant, MD, DMSc Jens Peter Kampmann, offered to set up and run a registry of these new treatment forms (the Danish Registry for Biological Therapies in Rheumatology). In October 2000 the registration started in a joint effort between the Danish Society of Rheumatology and the Danish Institute for Rational Pharmacotherapy.

Until January 1, 2004 the registry could be found at the Danish Institute for Rational Pharmacotherapy, and this institute also handled the daily work including the financing. The registry was then transferred to Hvidovre Hospital. The steering committee still includes representatives from the Danish Society of Rheumatology as well as the Danish Institute for Rational Pharmacotherapy. In the spring of 2004 the name of the registry changed to DANBIO.

In 2006 it was decided to merge DANBIO with the Danish Rheumatology Registry (DRD, Dansk Reumatologisk Database) under the name of DANBIO-DRD.

Since January 1, 2006 the registry has been web-based. Following a transition phase all departments have switched to web-based reporting. This presents a major advantage with instantaneous feedback to the attending doctor on the patient's status.

In 2011 the newest version of Danbio-online was put into use (version 4.0). With this version the user interface is even more user-friendly, and it has become simpler to register patients regardless of their treatment.

Longitudinal registration

Rheumatoid arthritis is a chronic non-curable disease. Therefore, lifelong monitoring and treatment are needed. The patients are recorded in the registry when they are first diagnosed (this started in 2006) or at the time of introducing a biological treatment. When first entering a patient in the registry a core data set is registered. During follow-up visits the patient's disease activity, treatment, treatment effect, adverse events during the treatment etc. are registered. In case of treatment discontinuation (termination) the cause of termination is registered.

Examples of the variables registered in DANBIO are presented in on pages 10-15.

From the autumn of 2008 the following minimum requirements apply to for registration:

- All newly referred patients with rheumatoid arthritis are to be registered regardless of treatment.
- All patients with rheumatoid arthritis starting biological treatment are to be registered.
- Core data are registered at the first visit.
- Follow-up data regarding treatment, disease activity and adverse events are registered 2 times a year (for patients visiting less often registration takes place at every control visit).
- X-rays of hands, wrists and front feet are taken at baseline and after 1, 2, 5, and 10 years. Change of treatment constitutes a new baseline.
- In principle, patients are followed in the registry on a lifelong basis.

Since the start of the registry, at total of 9 547 patients with rheumatology have been given biological treatment (as of January 2012). Hereof 5446 patients with rheumatoid arthritis, 1520 with ankylosing spondylitis, 1394 with psoriatic arthritis, and 1214 with other diagnoses

(including not registered). Some of the patients discontinued treatment, and in 2011, at total of 7094 patients received treatment with biologics, hereof 3938 with rheumatoid arthritis.

Touch screen for patient registration of disease activity

In May 2008 a "kiosk solution" was put into use, see photos below. With this touch screen, web-based solution, patients can carry out their own registration of disease activity in the waiting room, so that all relevant information subsequently is electronically available for the consultation with the doctor. This solution is implemented nationwide in Denmark since 2009.

The patients can answer a number of questions regarding their rheumatic disease in the waiting room. It is done on a touch screen and requires no qualifications. According to many rheumatic patients with impaired hand function, it is easier to use the screen than to complete a printed questionnaire using a ball pen.

Examples of touch screen questions are presented in figure 1-5 on the following pages.

Figure 1: The patient enters his/her civil registration number and diagnosis. Subsequently, he/she answers questions relating to the disease, see the next figure.

Figure 2: Example of a question to a patient with rheumatoid arthritis (question: Are you able to cut your meat? [Reply options: Without any difficulty / With some difficulty / With much difficulty / Unable to do so]). The replies are used to calculate the HAQ score.

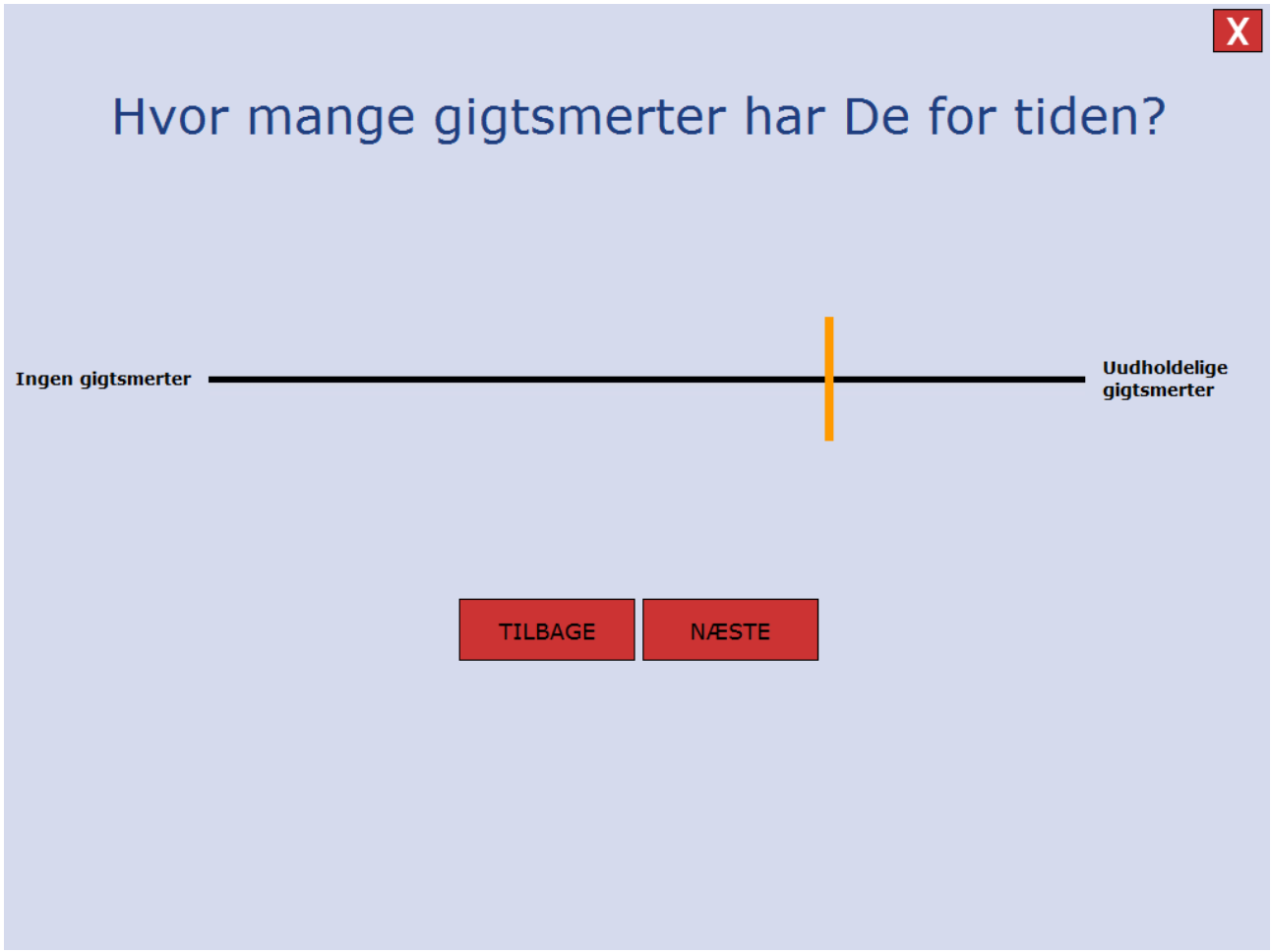


Figure 3: Example of a visual analogue scale used by the patient to indicate his/her pain level (question: How much pain have you had over the past week? Place a mark on the line below to indicate how severe your pain has been.). The answer is converted into a number between 0 (no pain) and 100 (pain as bad as it could be).

Figure 4. In the doctor's office the patient and the doctor together review the patient's answers and the doctor's own examinations, and the patient can keep track on whether the disease is treated adequately.

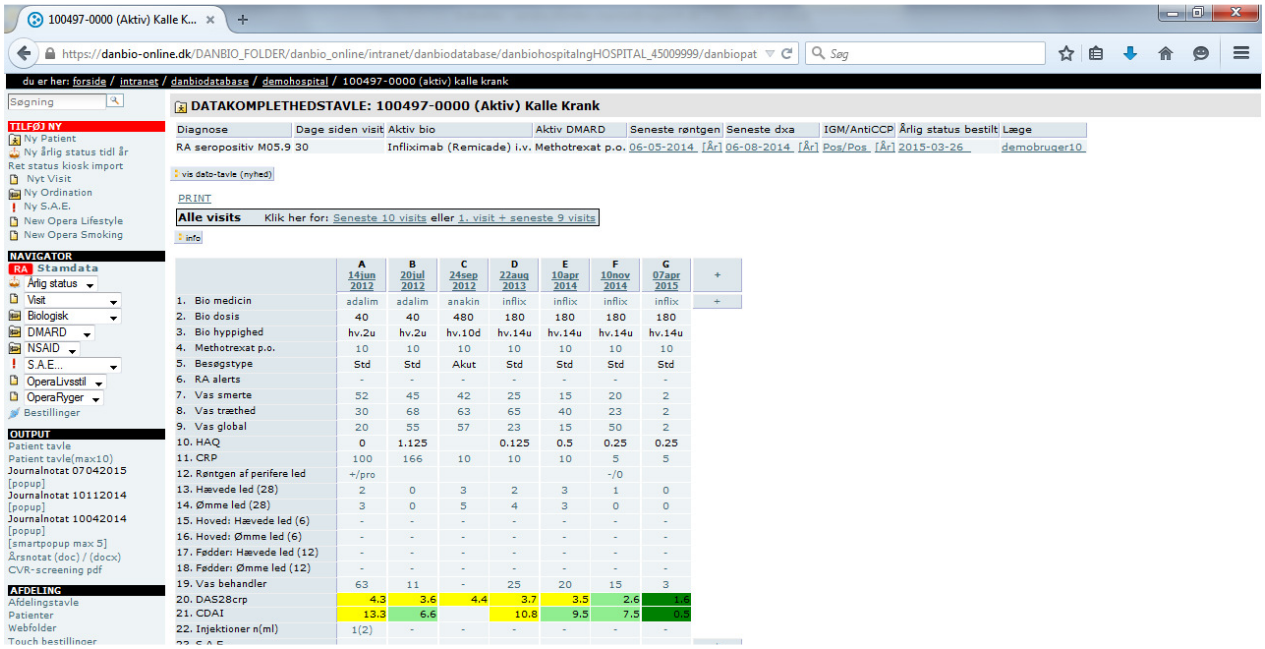


Figure 5. Patient scoreboard in DANBIO-online. The so-called patient scoreboard that provides the doctor and the patient with a comprehensive view of the treatment. The patient's disease is followed over time. Red: Severely active disease. Yellow: Moderately active disease. Green: Mildly active disease.

Inclusion ratio and data quality

Inclusion ratio for biological treatment

The registry inclusion ratio has been estimated several times. In 2002 the inclusion ratio was estimated to be 80-90% (1). In 2010 the inclusion ratio was 92%.

In 2010 the inclusion ratio was estimated by asking all Danish departments of rheumatology in writing to provide information about the number of patients in biological treatment as of January 1, 2010. The information collected was compared to the number of patients in the registry as of January 1, 2010.

Open source IT solution

- The DANBIO-IT solution consists of: A nationwide web-based solution: www.danbio-online.dk
- A combined PC and server solution for data analysis
- A touch screen solution for the patients to use in the waiting room
- A PC solution for display and validation of Dicom-based X-rays

www.danbio-online.dk uses Linux and FreeBSD as the server platform. The clinical patient registry was developed in zope, plone (www.plone.org) in combination with R (www.r-project.org) and MySQL (www.mysql.org).
The PC solution is based on Cardiff TELEform in combination with Microsoft Access integrated with a digital archive in Apache, php, MySQL (www.apachefriends.org), in which the scanned forms are stored.

The combined PC and server solution for data analysis is based on MySQL in combination with R. The PC solution for X-rays will be based on osirix (http://www.osirix-viewer.com/) and dicom3tools (http://www.dclunie.com/dicom3tools.html), among others.

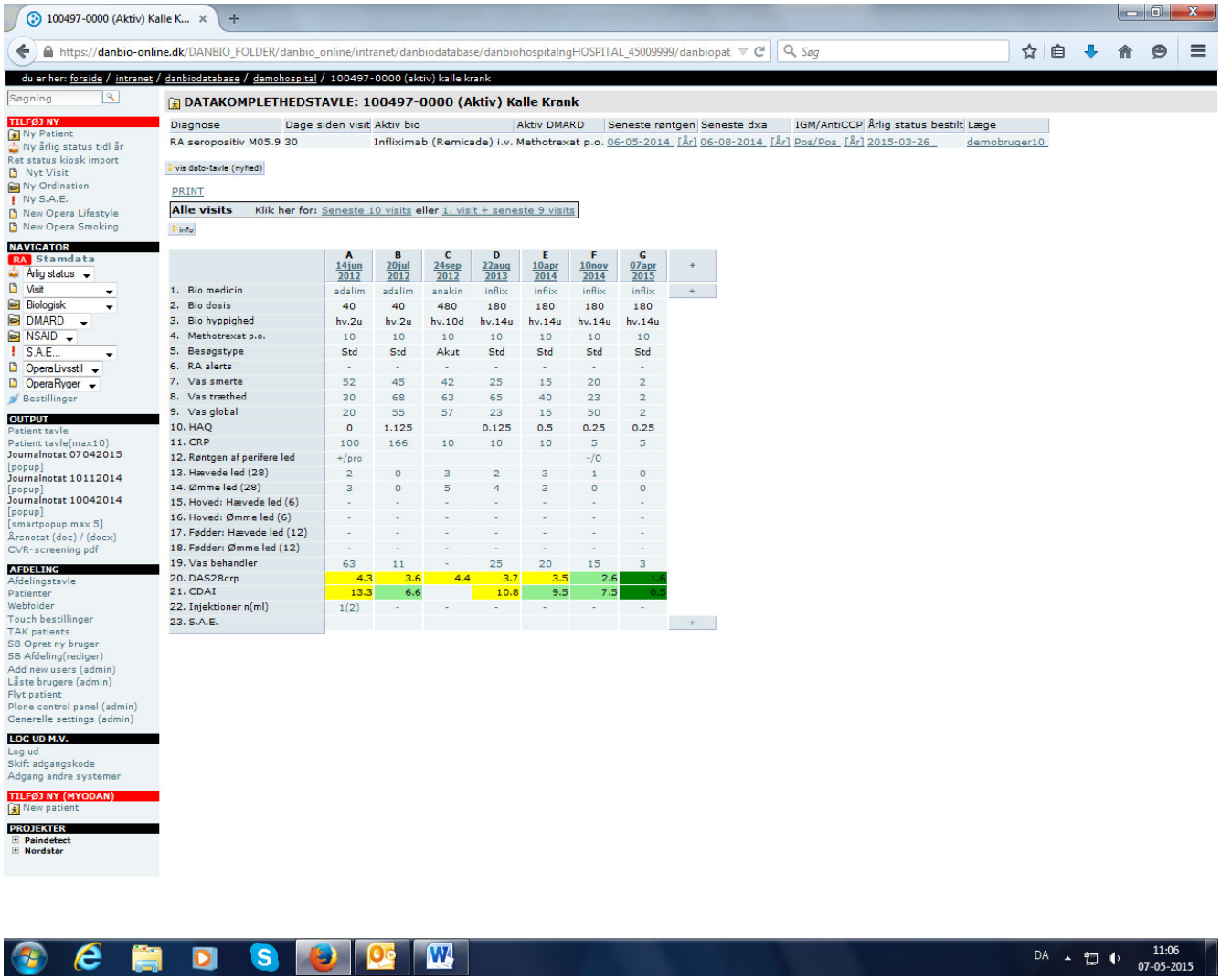
Apart from TELEform and Microsoft Access all programmes used and adjustments made are open source, which implies that they are used again without licence fees in other projects – in the health sector among others – in Denmark and in the other European countries. The rheumatologists in Iceland have established the registry "ICEBIO", which is a copy of the DANBIO IT platform for use for the patients in Iceland.

The DANBIO IT platform has been reviewed by the East Centre of Competence[3] in accordance with the basic requirements set out for nationwide clinical quality registries. Based on this, the registry IT platform has been approved by the Danish Regions.

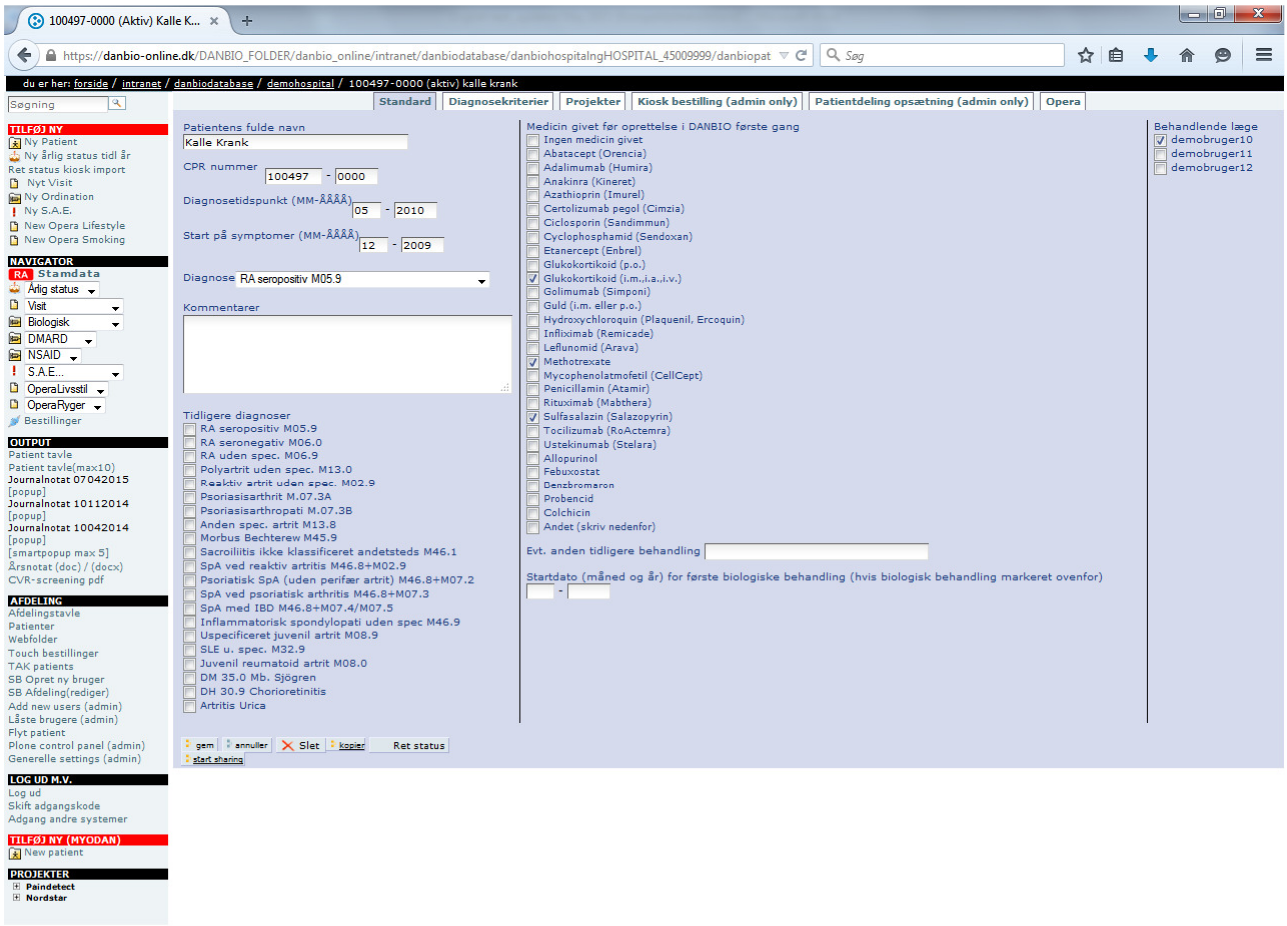
Publications

For an updated list of publications (peer-rewieved papers and abstracts), please see the most recent Annual Report or www.danbio-online.dk/om-danbio/formidling/publikationsliste.

Examples of the variables registered in DANBIO



The patient scoreboard provides an overview of treatment, disease activity, etc.


100497-0000 (Aktiv) Kalle K...
https://danbio-online.dk/DANBIO_FOLDER/danbio_online/intranet/danbiodatabase/danbiohospitalngHOSPITAL_45009999/danbiopat
Søg
du er her: forside / intranet / danbiodatabase / demohospital / 100497-0000 (aktiv) kalle krank
Søgning
TILFØJ NY
Ny Patient
Ny årlig status tidl år
Ret status kiosk import
Nyt Visit
Ny Ordination
Ny S.A.E.
New Opera Lifestyle
New Opera Smoking
NAVIGATOR
RA Stamdata
Årlig status
Visit
Biologisk
DMARD
NSAID
S.A.E...
OperaLivsstil
OperaRyger
Bestillinger
OUTPUT
Patient tavle
Patient tavle(max10)
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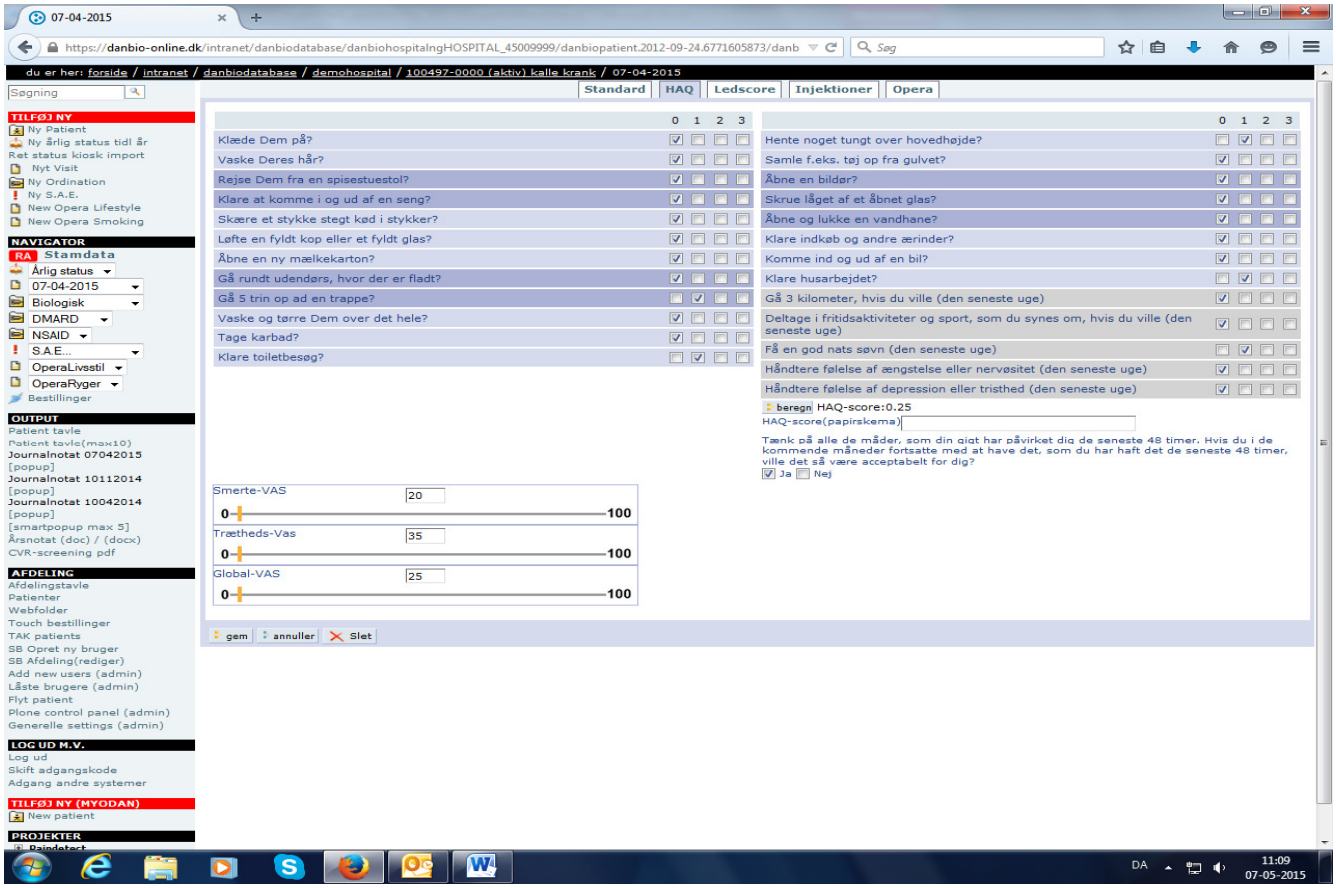
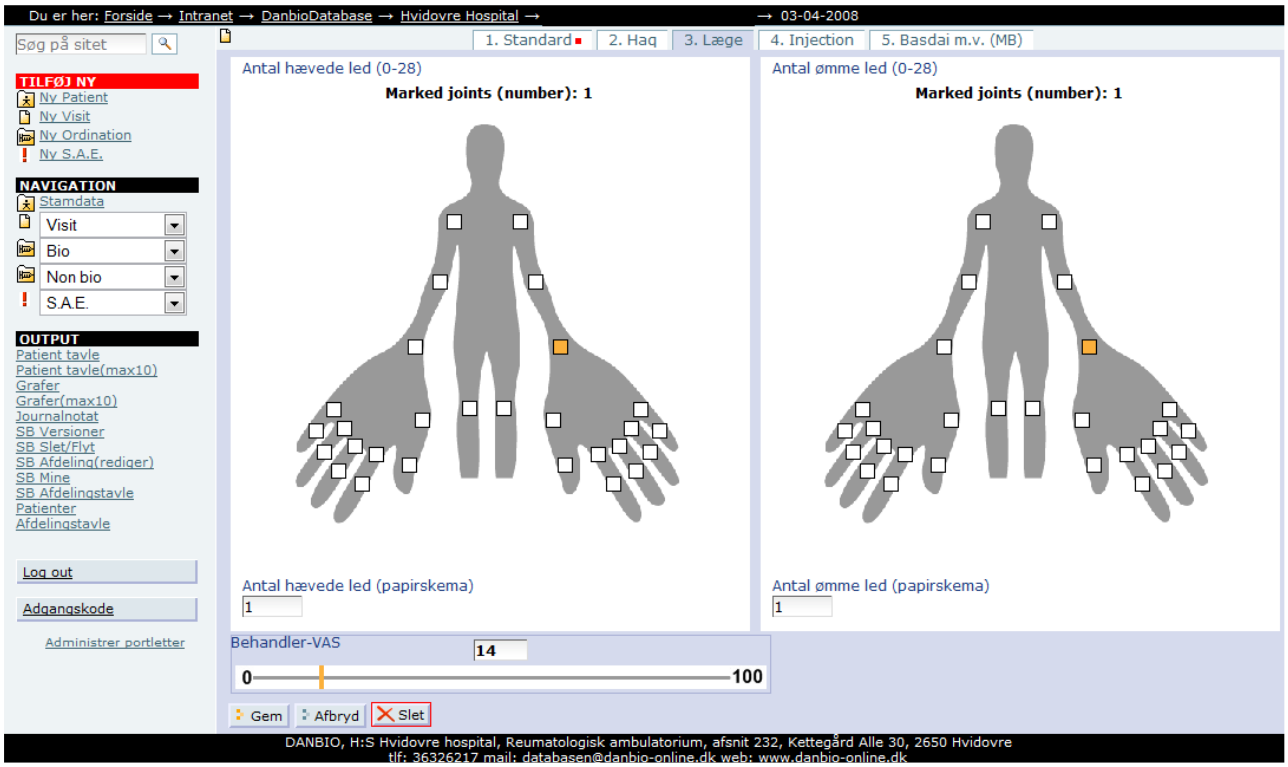
[popup]
Journalnotat 10112014
[popup]
Journalnotat 10042014
[popup]
[smartpopup max 5]
Årsnotat (doc) / (docx)
CVR-screening pdf
AFDELING
Afdelingstavle
Patienter
Webfolder
Touch bestillinger
TAK patients
SB Opret ny bruger
SB Afdeling(rediger)
Add new users (admin)
Låste brugere (admin)
Flyt patient
Plone control panel (admin)
Generelle settings (admin)
LOG UD M.V.
Log ud
Skift adgangskode
Adgang andre systemer
TILFØJ NY (MYODAN)
New patient
PROJEKTER
Paindetect
Nordstar
Standard
Diagnosekriterier
Projekter
Kiosk bestilling (admin only)
Patientdeling opsætning (admin only)
Opera
Patientens fulde navn
Kalle Krank
CPR nummer
100497 - 0000
Diagnosetidspunkt (MM-ÅÅÅÅ)
05 - 2010
Start på symptomer (MM-ÅÅÅÅ)
12 - 2009
Diagnose
RA seropositiv M05.9
Kommentarer
Tidligere diagnoser
RA seropositiv M05.9
RA seronegativ M06.0
RA uden spec. M06.9
Polyartrit uden spec. M13.0
Reaktiv artrit uden spec. M02.9
Psoriasisarthrit M.07.3A
Psoriasisarthropati M.07.3B
Anden spec. artrit M13.8
Morbus Bechterew M45.9
Sacroiliitis ikke klassificeret andetsteds M46.1
SpA ved reaktiv artritis M46.8+M02.9
Psoriatisk SpA (uden perifær artrit) M46.8+M07.2
SpA ved psoriatisk arthritis M46.8+M07.3
SpA med IBD M46.8+M07.4/M07.5
Inflammatorisk spondylopati uden spec M46.9
Uspecificeret juvenil artrit M08.9
SLE u. spec. M32.9
Juvenil reumatoid artrit M08.0
DM 35.0 Mb. Sjögren
DH 30.9 Chorioretinitis
Artritis Urica
Medicin givet før oprettelse i DANBIO første gang
Ingen medicin givet
Abatacept (Orencia)
Adalimumab (Humira)
Anakinra (Kineret)
Azathioprin (Imurel)
Certolizumab pegol (Cimzia)
Ciclosporin (Sandimmun)
Cyclophosphamid (Sendoxan)
Etanercept (Enbrel)
Glukokortikoid (p.o.)
Glukokortikoid (i.m.,i.a.,i.v.)
Golimumab (Simponi)
Guld (i.m. eller p.o.)
Hydroxychloroquin (Plaquenil, Ercoquin)
Infliximab (Remicade)
Leflunomid (Arava)
Methotrexate
Mycophenolatmofetil (CellCept)
Penicillamin (Atamir)
Rituximab (Mabthera)
Sulfasalazin (Salazopyrin)
Tocilizumab (RoActemra)
Ustekinumab (Stelara)
Allopurinol
Febuxostat
Benzbromaron
Probencid
Colchicin
Andet (skriv nedenfor)
Evt. anden tidligere behandling
Startdato (måned og år) for første biologiske behandling (hvis biologisk behandling markeret ovenfor)
-
Behandlende læge
demobruger10
demobruger11
demobruger12
gem
annuller
Slet
kopier
Ret status
start sharing

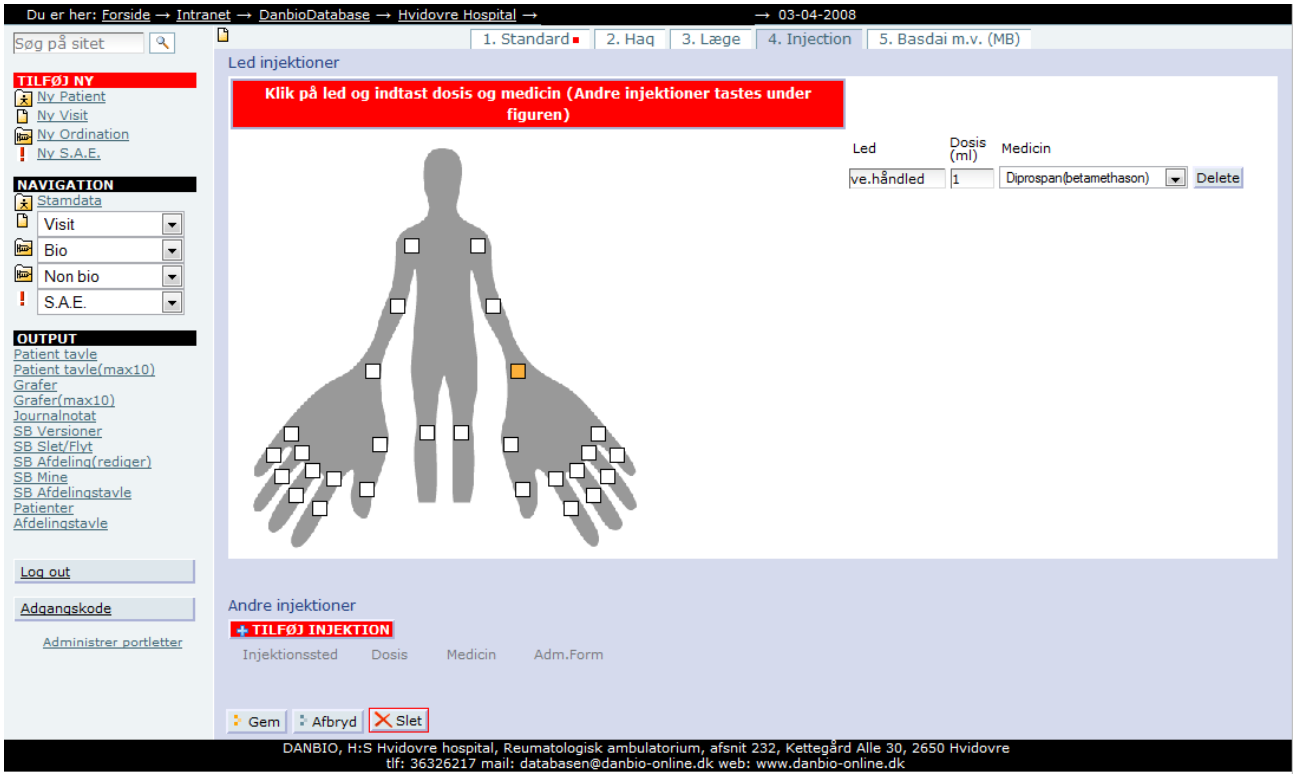
Core data.



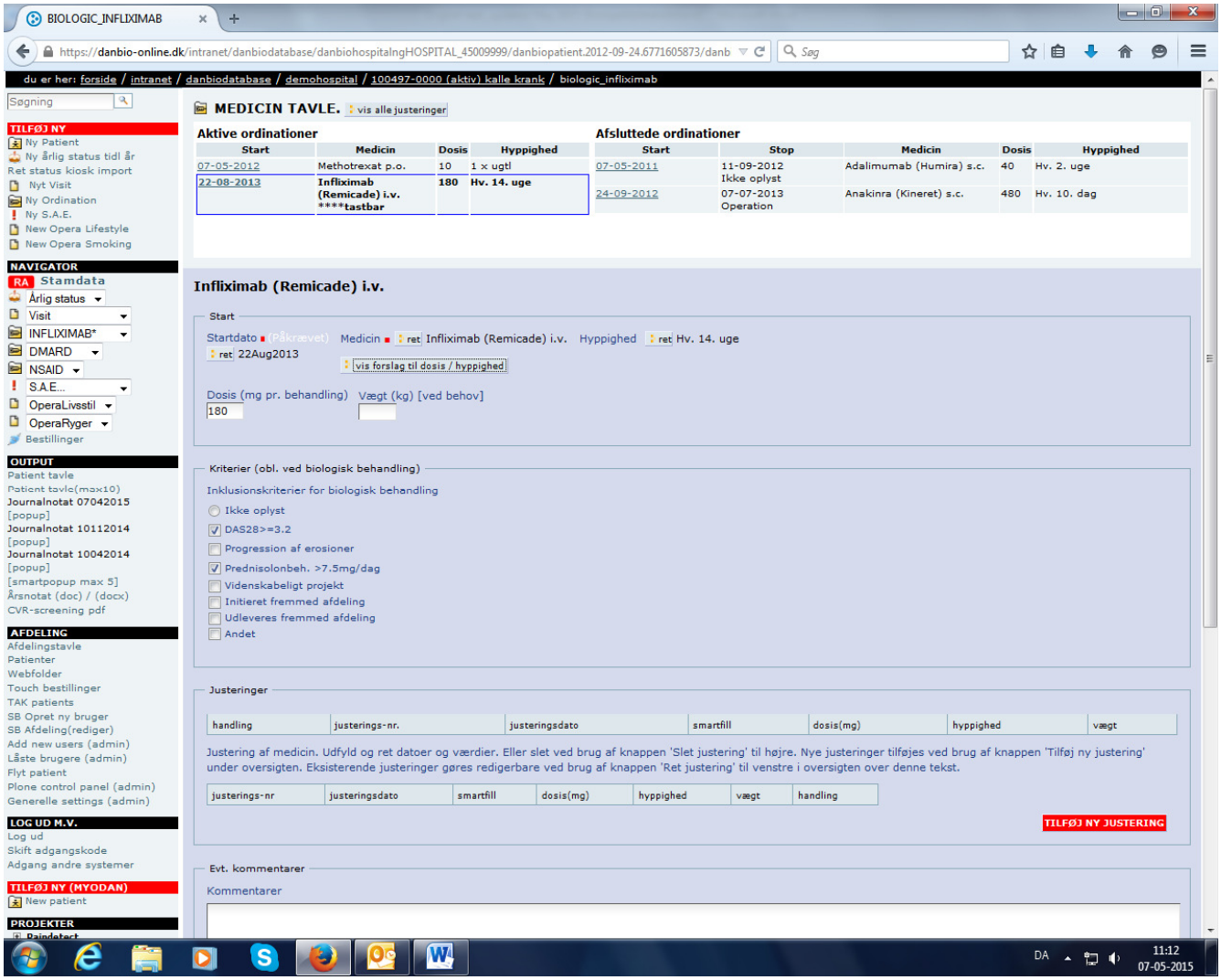
Patient's functional capacity, pain, fatigue, and quality of life.



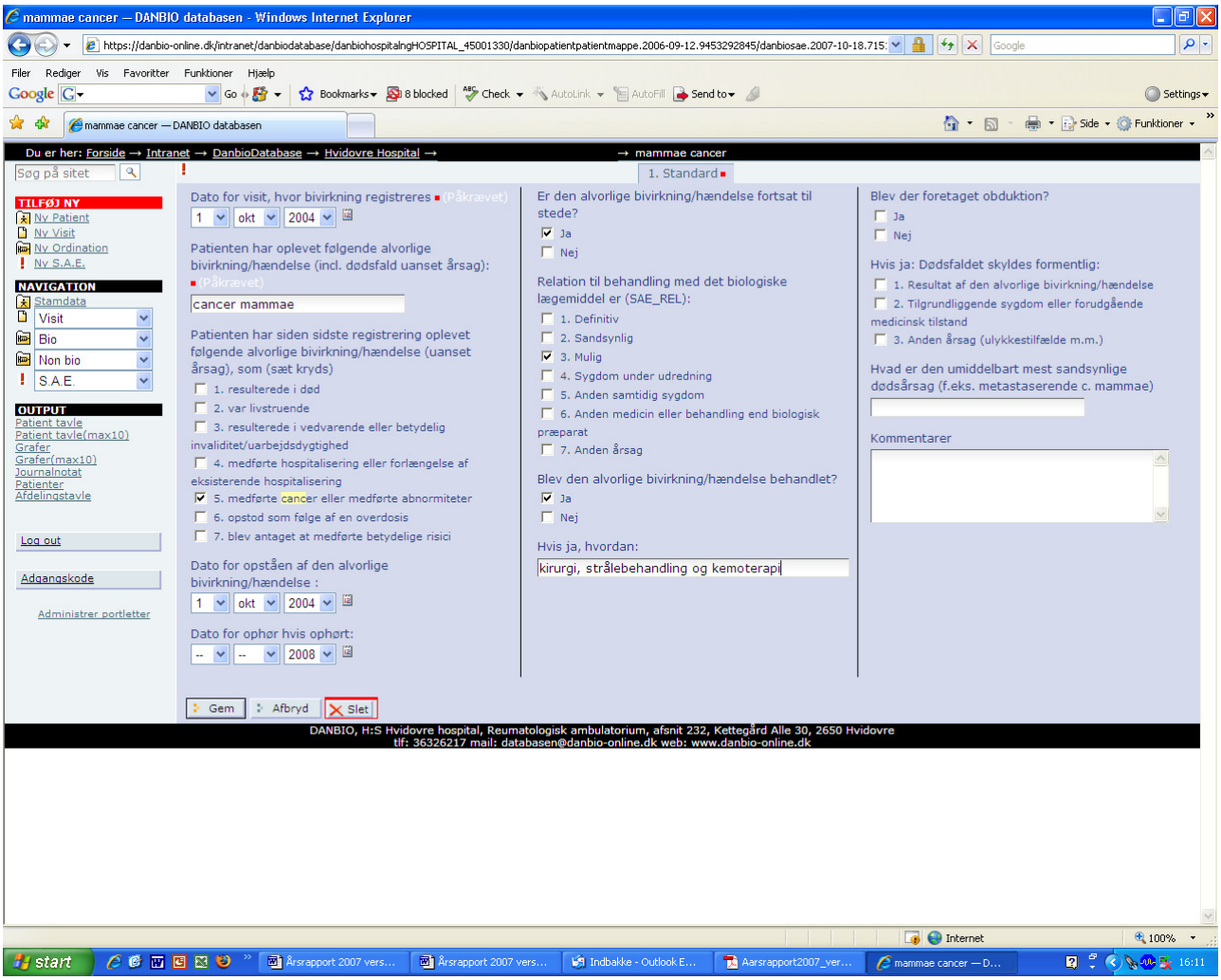
The doctor's registration of tender and swollen joints.



Registration of joint injections.



The prescription site. This site provides an overview of active and terminated treatments.



Severe adverse events are reported to DANBIO, and a message is also sent automatically to the Council for Adverse Drug Reactions of the Danish Medicines Agency.