Governance of the Risk-sharing Scheme

**Steering group**
Oversee the implementation of the Scheme
- **Membership**
  - DH (Chair)
  - ABN
  - MS Society
  - Chair of SAG
  - Bayer Schering Pharma
  - Biogen Idec Inc
  - Merck Serono
  - Teva/Taro-aventis

**Scientific Advisory Group (SAG)**
Advise on technical aspects of the scheme and monitor the conduct and progress of the study
- **Membership**
  - Scientific experts including research scientists, epidemiologists, neurologists, and health economists
  - MS Trust (secretariat)
  - Observers
  - DH representatives
  - Clinical leads
  - Manufacturers’ Medical Directors
  - NICE

**Funders group**
Consider factors that may impact on costs and the contract including those agreed on initiation of the scheme
- **Membership**
  - DH
  - Bayer Schering Pharma
  - Biogen Idec Inc
  - Merck Serono
  - Teva/Taro-aventis
  - MS Trust

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**The DH Risk-sharing Scheme for MS**
**MOVING CLOSER TO THE ANSWER**

**BENEFITS OF THE RSS**
- A major investment in MS infrastructure as part of the Scheme
- Data on a significant cohort of data on treated people with MS for future reference
- An improved economic model for MS to answer the cost efficacy question
- Partnership working between clinicians, the DH, Biogen Idec, Bayer, Merck Serono, and Teva
The DH Risk-sharing Scheme was set up in 2002 and is due to complete in 2015.

- **10 years** successful collaboration with **75 centres** across the UK
- **Ethos of the Scheme** remains unchanged - to ensure the cost effective provision of Avonex, Betaferon, Copaxone and Rebif across the UK
- **5,341 people** with MS eligible and treated. 4,717 ongoing (<12% lost to follow up)
- **10 year follow up** of the cohort with planned completion 2015
- **2 year data published** in BMJ. Deficiencies of the NICE discrete annualised Markov model identified and development of new models initiated by Scientific Advisory Group. The need for a more suitable natural history database demonstrated.
- **New models** – Continuous Markov and Repeated Measures developed. New natural history database from Vancouver accessed.
- **Currently 4 year data** being used to validate the models under supervision of the Scientific Advisory Group.
- **Final agreed model** will then be applied to 6 year data and cost efficacy calculations performed.

### Key Considerations for Maximising Data Collection

#### Annual Reviews – AR 10s now underway
- Work with your CRA to identify when annual reviews are due
- Individual patient trackers are maintained by your CRA and available to help you with managing appointment schedules
- Be familiar with how clinic appointments are managed
- Caution with centralised booking systems, ensure they are aware of the importance of annual visits

#### EDSS Score
- MREC approval now in place for Telephone EDSS for patients with an EDSS score of 6.5 or above.
- Telephone EDSS can be performed by a trained MS Nurse
- Local training of the MS nurses can be carried out by the Principal Investigator
- Training packages and further advice on this can be obtained from Dr Martin Duddy, Clinical Lead

#### Research opportunities
- Access to the largest cohort of treated people with MS for research projects that may benefit from using the data.
- Clinical leads happy to discuss the data or any potential projects.

#### Patients who Stop DMT
- Important that follow up continues and EDSS scores are recorded to maximise the validity of the data
- Experience tells us that follow up can be difficult if people with MS no longer seen in clinic
- Use of Telephone EDSS or follow up at other clinics e.g. Rehabilitation
- Make sure your CRA or the Clinical Leads are aware of any local issues

#### Site Resources
- If you foresee any changes at a local level that may impact on the collection of the data make sure that your CRA or the Clinical leads are aware as soon as possible
- Based on experience gained from the centres over the years help may be available with short or long term solutions.

### Contact details
- Dr Jackie Palace, Clinical Lead/Chief Investigator: Jacqueline.palace@ndcn.ox.ac.uk
- Dr Martin Duddy, Clinical Lead: Martin.Duddy@nuth.nhs.uk
- Clare Barclay, Parexel Project Director: Clare.Barclay@parexel.com
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