# Survey[1] on SE quality registries drug information 2015

| 1. Administrative information | | |
|---|---|---|
| **1. 1 Name on Quality registry in Swedish** | | |
| | | |
| **1.2 Name on Quality registry in English** | | |
| | | |
| **1. 3 Registry holder** | | |
| | | |
| **1. 4 Reporter** | | |
| | | |
| **Contact point/e-mail** | | |
| | | |
| **Reporting date** | | |
| | | |
| **1. 5 Scientific contact (if other than stated above)** | | |
| | | |
| **1. 6 Official website in Swedish** | | |
| | | |
| **1. 7 Is information concerning the registry available in English?** | Yes ☐ | No ☐ |
| If yes, please provide link to appropriate website | | |

| 2. Basic information regarding current status of registry |
|---|
| **2. 1** Which are the main diagnosis/indications included in the registry? |

[1] Det går att förflytta sig genom dokumentet med följande tangenter: Tab., Page-up eller ”pil”. Enklast markeras kryssrutor med mellanslagstangenten. Dokumentet är låst för endast kunna fylla i befintliga ”gråmarkerade” textrutor, Word tappar då en del funktioner. Större textpartier skrivs lämpligen i annat dokument och klistras in här, alternativt kan hänvisning anges i resp. fråga till bifogad bilaga/appendix.

| |
|---|
| **2. 2** If your registry contain sub registries, please provide name on registry and main diagnosis/indication included: |
| **2. 3** Total cumulative no of patients included: |
| **2. 4** No of patients included per year (approx. mean last 3 years): |
| **2. 5** No of participating center's/clinics out of eligible units : |
| **2. 6** No of eligible center's/clinics? |
| **2. 7** Proportion of eligible patients (=coverage) included in the registry (%) |
| **2. 8** How is coverage calculated? |

| **3. Data content/elements:** | **Yes** | **No** | **Explanatory details/ Specification** |
|---|---|---|---|
| **3. 1** Are patients participating in ongoing RCTs included in the registry? (Y/N)<br>RCT= Randomized Clinical Trials | ☐ | ☐ | |
| **3. 2** Are RRCT possible to perform within your registry? (Y/N)<br>RRCT= Randomized Registry Control Trials | ☐ | ☐ | |
| **3. 3** Is it possible to create a control group? (Y/N) | ☐ | ☐ | |
| **3. 4** Are patients from other countries included in the registry? (Y/N) | ☐ | ☐ | |
| **3. 5** Demographic limitations e.g. age group, geographical? (Y/N) | ☐ | ☐ | |
| If Yes, please specify | | | |

| **4. Data elements registered at inclusion in registry[2]** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **4. 1** Age (Y/N) | ☐ | ☐ | |
| **4. 2** BMI (Y/N) | ☐ | ☐ | |
| **4. 3** Sex (Y/N) | ☐ | ☐ | |

[2] If Yes, please specify measurements or if feasible refer to appendix/website

| | | | |
|---|---|---|---|
| **4. 4** Diagnosis (Y/N) | ☐ | ☐ | |
| **4. 5** Comorbidities[2] (Y/N) | ☐ | ☐ | |
| **4. 6** What terminology for coding of diagnosis and comorbidity used is used? | | ☐ ICD-10<br>☐ Other<br>☐ Free text | |
| **4. 7** Time point for disease onset (Y/N) | ☐ | ☐ | |
| **4. 8** Disease activity/state[2] (Y/N) | ☐ | ☐ | |
| If Yes , please specify used measurement[2] | | | |

| **5. Medication - Drug of interest** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **5. 1** Is indication for treatment with drug of interest recorded in the registry? (Y/N) | ☐ | ☐ | |
| **5. 2** If yes, what terminology for coding of indication is used? | | | |
| **5. 3** What elements concerning medication are recorded? | | | |
| – Product (Y/N) | ☐ | ☐ | |
| – Substance (Y/N) | ☐ | ☐ | |
| – ATC code (Y/N) | ☐ | ☐ | |
| – Dosage (Y/N) | ☐ | ☐ | |
| – Duration/exposure (Y/N) | ☐ | ☐ | |
| – Therapy start/stop date (Y/N) | ☐ | ☐ | |
| – Is reason for stop/switch to other drug registered (Y/N) | ☐ | ☐ | |
| **5. 4** Is concomitant medication recorded in your registry? (Y/N) | ☐ | ☐ | |

| **6. Elements registered at follow-up visits**: | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **6. 1** Is follow-up visits recorded in your registry? (Y/N) | ☐ | ☐ | |
| **6. 2** Are follow-up visits scheduled at regular intervals? | ☐ | ☐ | |
| If Yes, please specify intervals | Regularly ☐ If so, years or months<br>AD hoc ☐<br>Both ☐ | | |
| **6. 3** Are patients lost to follow-up registered? (Y/N) | ☐ | ☐ | |
| **6. 4** Are reasons for loss to follow-up registered? (Y/N) | ☐ | ☐ | |
| **6. 5** Maximum duration of long time follow-up? | | | |
| **6. 6** Is ongoing medication with drug of interest registered at follow-up? (Y/N) | ☐ | ☐ | |
| **6. 7** Is it possible to follow-up teratogenic events, due to medication with drug of interest? (Y/N) | ☐ | ☐ | |
| **6. 8** Is bio banking of DNA or tissue samples performed at inclusion (Y/N) | ☐ | ☐ | |
| **6. 9** Is bio banking of DNA or tissue samples performed at follow-up (Y/N | ☐ | ☐ | |

| **7. Outcome measures**[3] | **Yes** | **No** | ***Specified measurements, for further details refer to appendix, if feasible*** |
|---|---|---|---|
| **7. 1** Disease activity/state (Y/N) | ☐ | ☐ | |
| **7. 2** Organ damage e.g. renal damage (Y/N) | ☐ | ☐ | |

[3] If Yes, please specify measurements or if feasible refer to appendix/website

| | | | |
|---|---|---|---|
| **7. 3** Physical function (Y/N) | ☐ | ☐ | |
| **7. 4** Health economy/Cost-effectiveness data (Y/N) | ☐ | ☐ | |
| **7. 5** PROM (Y/N)<br>PROM= Patient Reported Outcome Measures | ☐ | ☐ | |
| **7. 6** PREM (Y/N)<br>PREM= Patient Reported Experiences Measures | ☐ | ☐ | |
| **7. 7** Is information on deaths and cause of death recorded? (Y/N) | ☐ | ☐ | |
| **7. 8** Quality of life (Y/N) | ☐ | ☐ | |
| **7. 9** Can you provide a summary list of used outcome measures in English, if needed (Y/N) | ☐ | ☐ | |
| **7. 10** Are the outcome measures the same as those used in clinical trials? (Y/N) | ☐ | ☐ | |
| **7. 11** Can long term safety be followed within your registry? (Y/N) | ☐ | ☐ | |
| **7. 12** If yes, is linkage to other data sources required? (Y/N) | ☐ | ☐ | |

| **8. Adverse event detection, processing and reporting** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **8. 1** Are adverse drug reactions (ADRs) registered within registry? (Y/N) | ☐ | ☐ | |

| | | | |
|---|---|---|---|
| If Yes –<br>• Is an approved terminology for coding of ADRs used, i.e. MedDRA[4]? (Y/N) | ☐ | ☐ | |
| • Does the registry provides means for web-based reporting of ADRs directly to MPA[5] | ☐ | ☐ | |
| **8. 2** Are events (not ADRs) interfering with medication (surgery, accidents etc.) registered? (Y/N) | ☐ | ☐ | |

| **9. Data capture/entry into database by:** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **9. 1** Web-based reporting into database? (Y/N) | ☐ | ☐ | |
| **9. 2** Is it possible for patients to enter PROMs directly into the registry by the web? (Y/N) | ☐ | ☐ | |
| **9. 3** Is data in the registry extracted directly from Electronic health records? (Y/N) | ☐ | ☐ | |
| **9. 4** If yes, percentage of participating healthcare center's with this opportunity? | | | |
| **9. 5** Is the database an integrated part of an electronic patient record system? (Y/N) | ☐ | ☐ | |

| **10. Quality control** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **10. 1** Is there a specifically qualified person for quality control of data? (Y/N) | ☐ | ☐ | |
| If yes –<br>please specify qualification (MD, research nurse, inspector etc.) | | | |

[4] MedDRA= Medical Dictionary for Regulatory Activities *www.meddra.org/*
[5] MPA= Läkemedelsverket

| | | | |
|---|---|---|---|
| **10. 2** Do you apply recommendations from specific international quality guidelines? (Y/N) | ☐ | ☐ | |
| If yes – please specify | | | |
| **10. 3** At what frequency is quality check performed (of raw data, delivery etc.)? | ☐ Regularly, e.g. every six months<br>☐ Randomly<br>☐ Event driven | | |
| **10. 4** At what level is registry data stored?<br>– Local/regional<br>– national<br>– multi-national | ☐<br>☐<br>☐ | | |
| **10. 5** Is missing data actively requested? (Y/N) | ☐ | ☐ | |
| **10. 6** Do you consider it possible to request additional information from treating physician, if needed by external stake-holders (e.g. pharma companies)? (Y/N) | ☐ | ☐ | |

| **11. Data analyses** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **11. 1** Performed by contract research organisation? (Y/N) | ☐ | ☐ | |
| **11. 2** At what level is data pooled for analyses? | ☐ Regional<br>☐ National<br>☐ Multi-national | | |

| **12. Ethics** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **12. 1** Is there written patient *information*? | ☐ | ☐ | |
| **12. 2** Is a formal patient *consent* obtained? | ☐ | ☐ | |

| | | | |
|---|---|---|---|
| If yes, how<br>– Written consent<br>– Verbal consent | ☐<br>☐ | ☐<br>☐ | |
| **12. 3** Does consent include an agreement to ask for follow-up information by e.g. a questionnaire, when needed from stake-holders (e.g. pharma companies)? (Y/N) | ☐ | ☐ | |
| **12. 4** Has an ethics committee approved the working procedures/ protocols of your registry? (Y/N) | ☐ | ☐ | |
| **12. 5** Have your registry adopted any specific code of conduct e.g. Helsinki declaration or ENCEPPs code of conduct? (Y/N) | ☐ | ☐ | |

| **13. Legal and organizational aspects** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **13. 1** If available, please provide an organogram of your registry set-up | | | |
| **13. 2** Who owns the registry data? | ☐ Health care professionals organisation<br>☐ Academic institution<br>☐ Pharma company<br>☐ Other | | |
| **13. 3** Is there a formal (written) agreement between participating centers regulating data handling and analytic procedures? (Y/N) | ☐ | ☐ | |
| **13. 4** Do you collaborate with pharma companies, based on data from the registry? (Y/N) | ☐ | ☐ | |
| **13. 5** If yes, are the results used by companies for regulatory purposes? (Y/N) | ☐ | ☐ | |
| **13. 6** Is patient privacy protected by specific measures? (Y / N ) | ☐ | ☐ | |

| | | | |
|---|---|---|---|
| **13. 7** If yes, how? Data/sample coding? | | | |
| **13. 8** Do you have a direct communication/ exchange of information with national regulatory agency (MPA)? (Y/N) | ☐ | ☐ | |

| **14. Communication and risk management** | **Yes** | **No** | **Comments** |
|---|---|---|---|
| **14. 1** Do you communicate results from your registry by scientific publications? (Y/N) | ☐ | ☐ | |
| **14. 2** If by other means, please specify e.g. annual report | | | |
| **14. 3** How many scientific publications has been published the last two years, based on data from your registry? | | | |
| **14. 4** When is feed- back given to reporting physician/clinics? | | | |
| – In real time (Y/N) | ☐ | ☐ | |
| – annually (Y/N) | ☐ | ☐ | |
| – AD HOC, in case of need e.g. safety problems (Y/N) | ☐ | ☐ | |

| **15. Financing by:** | | | **Approx. proportions (%) of total sum from each contributing part?** |
|---|---|---|---|
| **15. 1** Governmental/health care authorities? (Y/N) | ☐ | ☐ | |
| **15. 2** Industry? (Y/N) | ☐ | ☐ | |
| **15. 3** Research grants? (Y/N) | ☐ | ☐ | |