Executive Summary

One of the objectives of WP4 is to establish the EPAD Cohort and related data flows, databasing infrastructure, quality control/assurance and monitoring procedures. Data collected from TDCs via the Quintiles EDC will be curated and quality controlled by Quintiles in their database. At regular intervals this data will be transferred to the Analytical Database, hosted by Aridhia.

Aridhia will provide the infrastructure, software support and technical know-how required to establish the analytical database/platform. The platform is offered by Aridhia on a SaaS basis under the service name "AnalytiXagility". This will integrate EPAD Cohort data and other sources that will feed into the reporting and analytical work packages, like WP2. As necessary, dedicated collaborative workspaces, backed by a reliable, consistent level of information governance, security, backup and recovery for the programme, will be provided to working groups to carry out their project tasks. The EPAD analytical database will be hosted at the Stratified Medicine Scotland Innovation Centre, which has been established to operate just this sort of project and collaborative work between health, research and industry.

Aridhia will develop the Analytical Database starting from the current, in-house version of the Health Analytics Schema and implement: (a) Extensions that may be necessary to the core data model to capture the fields in the LCS protocol, and (b) A data integration workflow from the EDC data to provide a platform for analytical tasks. Optimising for analytics means providing data structures that facilitate the analytic workflow. Other principles to be considered when designing the HAS are: extensibility, modularity, data lineage and Good Clinical Practice.

The operating model is described whereby all LCS data collection is managed by Quintiles, and at monthly intervals an extract will be supplied to Aridhia. As these are received, Aridhia will build a new database instance using the Health Analytics Schema and take a snapshot from that which will be archived. After these latest files have been processed, an extract will be supplied to the required workspaces. Aridhia will also

provide support for EPAD analytics and reporting, comprising requirements for disease modelling, trial simulation and tracking and balancing the LCS.

For more information: info@epad.org