FDA CRF 21 part 11 Compliance and more

Company Name:	**Airon Telematica srl**
Product Name:	**Air-Tel e-CRF**
Contact Person:	**Andrea Maria De Rosa, MD**

Basic Parameters – General Questions	
Is the system CFR part 11 compatible?	☐ **Yes**
Is it possible to use the system besides EDC also for paper CRF?	☐ **Yes**
• *for creation of CRF which could be consequently printed and used as classic paper CRF*	☐ **Yes**
• *for input and processing of data coming from filled in paper CRF*	☐ **Yes**
Who administer your system for clinical trial process?	
• *administrator from your company*	☐ **Yes**
• *any person delegated to be administrator for the project*	☐ **No**
How many access levels exist in your system?	5
Please briefly describe: 1: Investigator; 2: PI, Sponsor (read-only); 3 CTA; 4: CRA/DM; 5: ADM *Any level can be crossed with sites permission from 1 to all sites* _____	
Is the system accessible entirely through web?	☐ **Yes**
On which database software is the system built?	**MS SQL**
Is it necessary to install any other application for using the system?	☐ **No**
If yes please specify: _____ _____	

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Audit Trail	
Does the system contain audit trail to document all modifications occurred during study process?	☐ **Yes**
Is it possible to print out global audit trail?	☐ **Yes**
Is it possible to print out audit trail per particular variables?	**Yes: Data Modifications, e-CRF versions, queries**

Database Creation	
Is it possible to setup appropriate format of variables during database creation process?	☐ **Yes**
If yes please specify parameters that could be defined for particular variables:	
• *minimal and maximal permitted value*	☐ **Yes for numerical values**
• *permitted empty field*	☐ **Yes (non blocking fields)**
• *predefined code list of permitted values*	☐ **Yes**
Is it possible to update above mentioned structure during data entry or data management process?	☐ **Yes**
Is it possible to input value not permitted by database structure?	☐ **No (only in 'Side' fields)**
Which format is applied to keep the date? *If numeric please specify the format:*	**Smalldatetime or Datetime** **Client choice**
Is it possible to program controls to check the coherence among particular variables (e.g. check dates between each other)?	☐ **Yes (coherence controls)**
Is it possible to program range checks during database creation?	☐ **Yes (and converted for different Measure Units)**
Is it possible to run range checks automatically?	☐ **Yes (usually active while data entry)**

Particular Data Management Process Parameters	
Option to import external data *If YES:*	☐ **Yes**
• *Which format is acceptable for import?*	Excel Access MS Sql
• *Is fixed structure of imported file necessary for import?*	☐ **No (data can be recoded)**
DCF tracking system (table with DCF overview)	☐ **Yes (Query management)**
Double data entry	☐ **Yes (only if required)**
Multiple data entry (investigator, CRA, opA, ..)	☐ **Yes (with anti-conflict controls)**

Option to have interface in several languages	☐ **Yes**
Option to lock the database anytime during study process	☐ **Yes (by single forms/pages)**
Automatic generation of annotated CRF	☐ **Yes**
Export data anytime during study process	☐ **Yes**
Is the system CDISC compatible? (define.xml, SDTM)	☐ **Yes (in xml format)**

System Validation Documentation	
Is documented validation of system available including validation of particular system components?	☐ **Yes GAMP 5.1**

Additional Questions	
Does the system contain query management process?	☐ **Yes**
Is it possible to export data directly to SAS?	**Usually done by Statistician**
Is it possible to generate data listings corresponding to DB structure?	☐ **Yes**
Is it possible to match your system with medical coding dictionary (WHO Drug, MedDRA) to manage automatic coding?	**It is possible to pre-define Drugs and SAEs fields**