

## 10.1.2 System Conformity

A computing system that processes information in ODM format can claim conformance to this standard only if it obeys the following rules.

1. Generated ODM files must satisfy all the correctness rules in the standard, both syntactic and semantic.
2. A receiving system must be able to read any ODM file that satisfies all the correctness rules in this standard, both syntactic and semantic.
3. ODM files must validate against the ODM schema for the ODM version indicated in the ODM root element.
4. Information included in generated ODM files must be accurate according to the rules of this standard as defined in this specification.
5. A receiving system must interpret information read from an ODM file accurately according to the rules of this standard as defined in this specification.
6. Generated ODM files need not include information that is not normally handled or stored by the generating system.
7. A receiving system may selectively ignore information read from an ODM file if that information is not normally handled or stored by the receiving system.
8. A receiving system may constrain the range of data values, keys, names, and so on, that it is capable of handling or storing.
9. Systems that receive ODM clinical data files but do not normally support one or more of the datatypes specified in section 2.14, should accept clinical data of the unsupported types as text.
10. All system limitations (rules 6 through 9) must be documented.
11. If conformity is dependent on certain modes or settings, this must also be documented.

OpenClinica's support for generated and received meets these constraints, including documentation of limitations (#10). The limitations are described in the Limitations section of this document.

Approved for publication by Cal Collins. Signed on 2014-04-02 2:55PM

Not valid unless obtained from the OpenClinica document management system on the day of use.