

A DICOM Compatible Format for Analytical Cytology Data, that can be Expressed in XML

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ABSTRACT

Flow Cytometry data can be directly mapped to the Digital Imaging and Communications in Medicine, DICOM standard. A preliminary mapping of list-mode data to the DICOM Waveform information Object will be presented. This mapping encompasses both flow and image list-mode data. Since list-mode data is also produced by digital slide microscopy, which has already been standardized under DICOM, both branches of Analytical Cytology can be united under the DICOM standard. This will result in the functionality of the present International Society for Analytical Cytology Flow Cytometry Standard, FCS, being significantly extended and the elimination of the previously reported FCS design deficiencies. Thus, The present Flow Cytometry Standard can and should be replaced by a Digital Imaging and Communications in Medicine, DICOM, standard.

Expression of Analytical Cytology data in any other format, such as XML, can be made interoperable with DICOM by employing the DICOM data types. A fragment of an XML Schema has been created, which demonstrates the feasibility of expressing DICOM data types in XML syntax. The extension of DICOM to include Flow Cytometry will have the benefits of 1) retiring the present FCS, 2) providing a standard that is ubiquitous, internationally accepted, and backed by the medical profession, and 3) interoperating with the existing medical informatics infrastructure.

Keywords: FCS, Flow Cytometry, Slide Microscopy, DICOM, Waveform, Software, XML, Standards, Medical Informatics

1. INTRODUCTION

Flow Cytometry Standard, FCS¹, has been a useful means for transferring and archiving flow cytometry data. A major success of Analytical Cytology is that it now produces clinically useful information, which should be accessible to the rest of the clinical laboratory information system. There are two ways to do this: translate the FCS data into the format of the clinical information system or extend the clinical information system to include the functionality of FCS. Digital Imaging and Communications in Medicine, DICOM, is a clinical information system standard, which already includes the functionality required for digital slide microscopy and can easily be extended to include flow cytometry. DICOM has been sponsored for microscopy by the appropriate association of clinicians, the American College of Pathologists. Since DICOM does include the functionality of FCS, it will be possible to translate FCS into DICOM, which will be necessary during the transition period. As previously described², the proposed third version of the Flow Cytometry Standard³, FCS 3.0, has significant technical flaws, which include: 1) a recursive structure, 2) lack of support for the ISO 8859-1 (Latin 1) eight bit character set, 3) the standard is not programming language independent, 4) it allows the user to select the sentinel character and permits the use of the same character as a sentinel for both the beginning and end of a value, and 5) it does not define the length of strings. FCS has very limited capabilities and use compared to DICOM.

DICOM includes the following descriptions of Information Objects of direct relevance to Analytical Cytology: Patient, Series, Specimen, Equipment, Slide-Coordinates Microscopic Image, Waveform, Structured Report, and Interpretation. The capacity of DICOM to describe an Analytical Cytology specimen including: Specimen Handling Precautions, Specimen Handling Special Requirements, Submitting Service, Specimen Accession Number, and Creation Time and Date of Accession has been previously described by Leif & Leif (1997)² and are described at length in the DICOM standard⁴. The elements describing the patient including: Name, Id #, Date of birth, Sex, Referring physician name(s), Referring physician phone, Referring institution, History/relevant clinical information and diagnoses, reason for FCM request, Previous relevant therapy, Previous FCM studies, and Other lab results (WBC, differential count) were described by Leif & Leif (1998)⁵. Therefore, the best choice is to directly use DICOM for Analytical Cytometry data. List-mode data previously presented a major problem to this mapping. An attempt was made⁵ to use the DICOM Curve information object. The Curve had disadvantages such as: the Number of Points (cells) was limited to 2¹⁶, and many of the items in FCS 3.0 were omitted. It had the advantage of including floating point representations of the data. The new DICOM waveform information object provides an excellent solution, which provides functionality that is superior to FCS. The addition of Structured Reporting^{6,7} provides a very powerful means to connect the data

with the end user of the data, the pathologist or other individual who makes a clinical decision based on the data.

2. MAPPING OF FCS TO DICOM

2.1. List-mode to DICOM Waveform

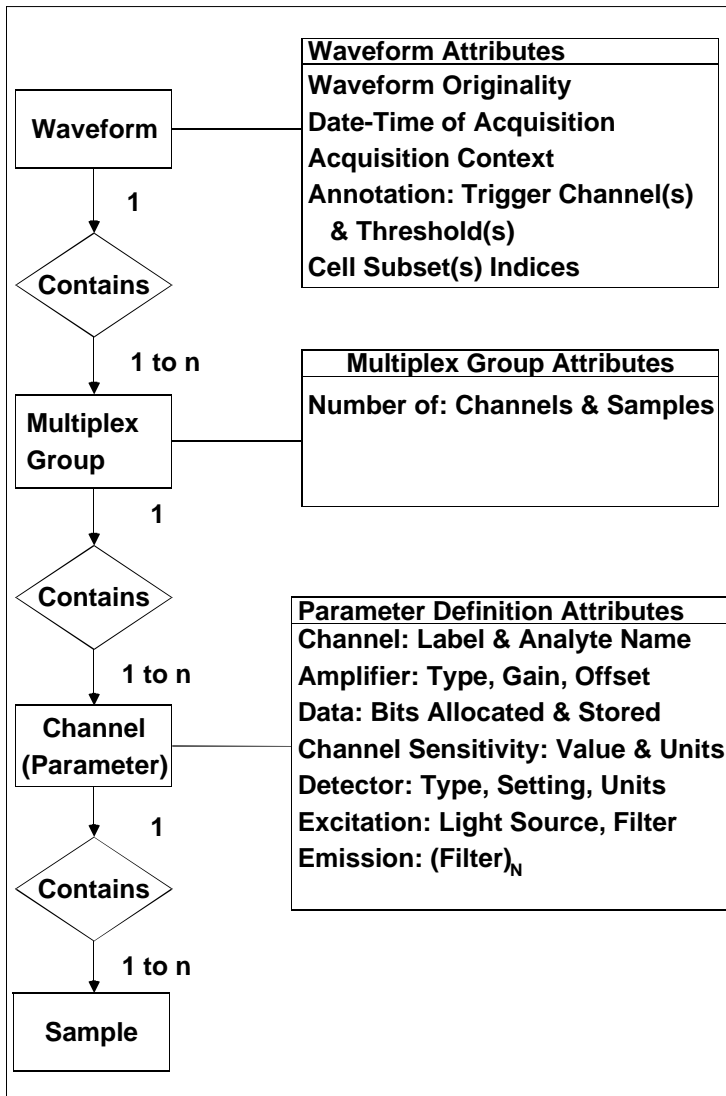


Figure 1. This figure is an adaptation of DICOM PS 3.3 - 2000, Figure J.5-1, DICOM Waveform Information Model, to Analytical Cytometry. The waveform corresponds to list-mode data. There is only one Multiplex Group for conventional list-mode data. Each Channel corresponds to a parameter; and each Sample is the vector or record that contains the data for an individual particle (cell).

Originality of the data, which has 2 values: original data collected by the instrument or derived data produced by some analytical process. Although FCS 3.0 employs an analysis section for this type of data, it does not provide an audit trail suitable for today's medical-legal environment. The second attribute is the start Date-Time of acquisition of the flow cytometry list-mode data or image data from which list-mode can be derived. The correspondence of this attribute and others with FCS equivalents is shown in Table 1. The Directory Information Module includes the name(s) of the data file(s) containing the data set. An individual file is specified by the Referenced File ID (0004,1500), which is the path including the file. This path has a maximum of 8 components, each with from 1 to 8 characters. DICOM can store the combination of date and time at the beginning

The text below describes how to map FCS list-mode data to the elements of DICOM Waveform information objects⁸. In order to completely identify the data elements the DICOM Data Element Tag will be given after the name of each of the data elements. The official version of the DICOM Standard must be purchased⁹. However, the 1999 "draft" is available on the Internet¹⁰ as Adobe Acrobat PDF files. DICOM is a large multivolume standard, which also includes supplements. Three volumes of the standard are relevant to this paper: Part 3: Information Object Definitions, Part 5: Data Structures and Encoding, and Part 6: Data Dictionary. Two supplements are also relevant: Supplement 23: Structured Reporting Storage SOP Classes⁶ and Supplement 30: Waveform Interchange⁸. The latter is essentially included in the 2000 version of Part 3. Unfortunately, it is not included in the 1999 version, which is available at this time, January 2001. Since Part 3, which describes the Information Objects is large, 665 pages, searching can be tedious. Besides the obvious use of the CONTENTS, a quick short way to find the pages where a data element is mentioned is to use the Acrobat Find with the DICOM Tag starting at the end of Part 3, where the Index of Tags is located.

2.1.1 Slide Microscopy & Flow Cytometry Modalities

At present, DICOM includes a Visible Light Slide-Coordinates Microscopic Image Information Object Definition, which has a Modality (0008,0060) specified to equal Slide Microscopy (SM). List-mode Flow Cytometry and Slide Microscopy data only differ in that the time of data acquisition is relevant to flow and the x and y coordinates on the slide are relevant to Slide Microscopy. Even though, a good argument could be made for these two Analytical Cytology branches to be considered one modality, the assignment to Slide Microscopy of SM necessitates the creation of a value for Flow Cytometry, FC.

2.1.2. Waveform Attributes

The first of these data elements shown in Figure 1 is the

of the data acquisition (0008,002A). The Channel Label for the Trigger parameter(s) and their threshold(s) are also attributes of the waveform.

Table 1 : Waveform

FCS 3.0 Name	FCS3.0 Description	FCS 3.0 Type	DICOM Data Type	Tag	Document & Location¹	Values
\$FIL	Name of the data file containing the data set.	String	Referenced File ID	(0004,1500)	D3.3 Table F.3-3 DIRECTORY INFORMATION MODULE	Up to 8 Code Strings each with a Max 8 Chars
\$BTIM	Clock time at beginning of data acquisition	Time: hh:mm:ss[:tt]	Acquisition Date/Time	(0008,002A)	D3.3 Table C.10-8 Waveform Identification Module Attributes	hh:mm:ss.sss
\$TR	Trigger parameter and its threshold.	String & Integer String	Channel Label	(003A,0203)	D3.3 Table C.10-9 Waveform Module Attributes	String Max 16 Chars
\$GnN	Name of gating parameter number n.	String	Channel Label	(003A,0203)	D3.3 Table C.10-9 Waveform Module Attributes	String Max 16 Chars
\$GnS	Name (Long) used for gating parameter n.	String	LOINC Component		LOINC Users' Guide Section 2.2.1.1 & Appendix A	String Max 64 Chars
\$COMP	Fluorescence compensation matrix	Float Array row-major order (D.DDD)	Analogous to Frame of Reference Transformation Matrix	To be created	D3.3 Table C.8-37-STRUCTURE SET MODULE ATTRIBUTES	Decimal String multiplicity Max 16

¹ In this and the succeeding tables, the DICOM locations are in the format D3.N. Where D3 is the abbreviation for DICOM Version 3 and N is the DICOM volume number. The Table numbers can be used to search a document.

The FCS Name (Long) that is used for the gating parameter n ($\$GnS$) maps to a Logical Observation Identifier Names and Codes (LOINC®)¹¹ element. The formatting of parameter names is discussed below in Section 2.1.4.

DICOM includes the use of Referenced Sample Positions (0040,A132). These are positions in one or more Channels in the Multiplex Group, which corresponds to flow cytometry list-mode. These positions are numbered starting with 1 and are defined in terms of: POINT = a single temporal point; MULTIPOINT = multiple temporal points; SEGMENT = a range between two temporal points; MULTISEGMENT = multiple segments, each denoted by two temporal points; BEGIN = a range beginning at one temporal point, and extending beyond the end of the acquired data; and END = a range beginning before the start of the acquired data, and extending to (and including) the identified temporal point. This capacity to specify a collection of individual events permits the identification of these events as members of a cell subset and replaces the functionality provided by the FCS Key Words: $\$CSMODE$, $\$CSVBITS$, and $\$CSVnFLAG$. The use of an index in DICOM as opposed to the addition of a parameter in the FCS list-mode data has the advantage of simplifying and increasing the execution speed of the software. Since the software can index through all of the data that applies to a specific cell subset, the subsets can be analyzed or rendered sequentially rather than simultaneously. These Referenced Sample Positions can also be applied to single channels and employed to gate the list-mode data. The elements of both the FCS Fluorescence Compensation Matrix and the DICOM Frame of Reference Transformation Matrix (3006,00C6) are listed in row-major order. Other information specific to the Acquisition Context are parts of the Visible Light Slide-coordinates Microscopic Image information object and will be discussed below.

2.1.3. Multiplex Group

A multiplex group is a collection of channels which are acquired synchronously. Although for a flow cytometers, some of the parameters can be acquired in sequence, all of the parameters for an individual particle (cell) are grouped together in a single list-mode file. Thus, they can be treated as one multiplex group. Similarly, in the case of Slide Microscopy, the data describing individual cells, which was derived from a large number of sequentially collected images, is stored as a single list-mode file or one multiplex group. A Multiplex Group has a Label (003A,0020), which is a short string of up to 16 characters. The first two items in Table 2 are FCS 3.0 required fields. These are: number of parameters ($\$PAR$), which maps to the Number of Waveform Channels (003A,0005) and the number of events in the data set ($\$TOT$), which maps to the Number of Waveform Samples (003A,0010), which has the needed range of 1 to 2^{32} . The Time step for time parameter ($\$TIMES$) maps to two DICOM data elements. The first is Channel Sensitivity (003A,0210), which is the nominal value the least significant bit measured and the second is Channel Sensitivity Units Sequence (003A,0211) which includes the units of measurement: seconds, milliseconds, etc. The last two items in Table 2 are new, but can be expressed as the Integer String DICOM data type.

Table 2 : Multiplex Group

FCS 3.0 Name	FCS 3.0 Description	FCS 3.0 Type	DICOM Data Type	Tag	Document & Location	Values
\$PAR	Number of parameters in an event	Integer String	Number of Waveform Channels	(003A,0005)	D3.3 Table C.10-9 Waveform Module Attributes	Unsigned 16 bit Integer
\$TOT	Total number of events in the data set.	Integer String	Number of Waveform Samples	(003A,0010)	D3.3 Table C.10-9 Waveform Module Attributes	Unsigned 32 bit Integer
\$TIME STEP	Time step for time parameter.	Float	Channel Sensitivity & Channel Sensitivity Units Sequence	(003A,0210) & (003A,0211)	D3.3 Table C.10-9 Waveform Module Attributes	Decimal String
\$ABRT	Events lost due to data acquisition electronic coincidence	Integer String	Integer String	To be created	No existing element	Integer String
\$LOST	Number of events lost due to computer busy.	Integer String	Integer String	To be created	No existing element	Integer String

2.1.4. Channels

Each of the Channels is described by a sequence that includes the equivalent information used in FCS to describe a parameter. A sequence is the DICOM format for an aggregate of objects. It is similar to a Pascal or Ada record, a C struct, and an XML sequence, which is an element that contains one or more other elements. The description of the Channel sequence starts with the Waveform Channel Number (003A,0202) which is equal to the FCS parameter number, n . Since the sequence construct is used, the value of n needs to be given only once; rather than, as in FCS, being included with each data element. The direct mapping between the FCS3.0 items, that describe a parameter and the DICOM data types that describe a channel is shown in Table 3. Of the 11 FCS items only two are required by the FCS 3.0 standard and 4 have a corresponding DICOM data element with a standard tag, one is a LOINC element, two are from Systematized Nomenclature of Human and Veterinary Medicine (SNOMED), and three are new and have to be created. LOINC and SNOMED data elements have been included in DICOM by coding schemes, which are designated by Coding Scheme Designator (0008,0102).

The name used for each parameter can be selected from the LOINC database¹¹. For instance, 522 items are listed in the LOINC CellMark Class. These start with CELLS.CD97/100 CELLS and end with BLASTS.TERMINAL DEOXYRIBONUCLEOTIDYL TRANSFERASE/100 BLASTS. The LOINC nomenclature presently describes test results; however, it can be used in a format suitable for Analytical Cytology. The LOINC database COMPONENT field “consists of three subparts: (1) the principal name (e.g. the name of the analyte or the measurement); (2) the challenge or provocation, if relevant, including the time delay, substance of challenge, amount administered, and route of administration; and (3) any standardization or adjustment.” Of these only the name is relevant. The name of the analyte consists of 3 subfields: [analyte].[subclass].[sub-subclass], which are separated by a period. The name of the analyte is a noun. The subclass can be specified as an antibody, AB or preferably at type of immunoglobulin. It would be very useful for Analytical Cytology to use the sub-subclass for the name of the label attached to the reagent, such as the fluorophore. For instance, Cells.CD4 IgG.Fluorescein. The LOINC database Component field can contain up to 150 characters; however, since only the first subpart has been specified, the DICOM Long String, which is limited to a maximum of 64 characters, is the appropriate mapping.

The FCS Amplification type for parameter n (\$PnE) can be represented by the DICOM Attribute Waveform Sample Interpretation (5400,1006) provided that Log is added to the list of enumerated values for this Data Element. Otherwise, a new, enumerated (Linear or Log) Data Element, which is represented by a code string, will have to be created. Particularly when a logarithmic representation of the data is employed, the Channel Offset (003A,0218) and Channel Maximum Value (5400,0112) should also be included in the sequence that describes the Channel.

In FCS, the type of data in the DATA segment (\$DATATYPE) includes ASCII, integer, and floating point. DICOM Waveforms presently only include integer data; however, these integers can effectively have four formats 8 and 16 bit signed and unsigned integers. Since, the FCS non-integer data types are not used for the preponderance of list-mode data and are usually employed in arrays smaller than 2^{16} , these can be handled, as previously suggested⁵, by the DICOM Curve Information Entity. As stated in the DICOM Standard, “Encoded Waveform Data of various bit depths is accommodated through the Waveform Bits Allocated (5400,1004) Data Element. This element defines the size of each waveform data sample within the Waveform Data (5400,1010). Allowed values are 8 and 16 bits.”

Table 3 Channel Sequence

FCS 3.0 Name	FCS3.0 Description	FCS 3.0 Type	DICOM Data Type	Tag	Document & Location	Values
\$PnN	Short name for parameter n.	String	Channel Label	(003A,0203)	D3.3 Table C.10-9 Waveform Module Attributes	String Max 16 Chars
\$PnS	Name used for parameter n.	String	LOINC Component		LOINC Users' Guide Section 2.2.1.1 & Appendix A	String Max 64 Chars
\$PnT	Detector type for parameter n.	String	String	To be created	D3.3 Table C.10-9 Waveform Module Attributes	String Max 16 Chars
\$PnV	Detector voltage for parameter n.	Decimal String	Detector voltage	To be created	D3.3 Channel Source Modifiers Sequence	Decimal String
\$PnE	Amplification type for parameter n.	Decimal String, Decimal String	Waveform Sample Interpretation	(5400,1006)	D3.3 Table C.10-9 Waveform Module Attributes. To be extended.	Code String 3 Chars Lin or Log
\$PnG	Amplifier gain used for acquisition of parameter n.	Decimal String	Amplifier Gain	To be created	D3.3 Channel Source Modifiers Sequence	Decimal String?
\$PnB (Binary)	Number of bits reserved for parameter number n	Integer String	Waveform Bits Allocated	(5400,1004)	D3.3 Table C.10-9 Waveform Module Attributes	8 or 16 Bits
\$PnR	Range for parameter number n	Integer String	Waveform Bits Stored	(003A,021A)	D3.3 Table C.10-9 Waveform Module Attributes	1 to Waveform Bits Allocated

Table 3 Channel Sequence

\$PnL	Excitation wavelength for parameter n.	Integer String	Excitation Filter	SNOMED TID =5, CID = 48	Table C.7.6.14.1.2-1 - DESCRIPTORS OF ACQUISITION CONTEXT	Integer String
\$PnF	Name of optical filter for parameter n.	String	Emission Filter	SNOMED TID =5, CID = 49	Table C.7.6.14.1.2-1 DESCRIPTORS OF ACQUISITION CONTEXT	String
\$PnP	Percent of emitted light collected by parameter n.	Decimal String	Channel Sensitivity Correction Factor	(003A,0212)	Table C.10-9 Waveform Module Attributes	Decimal String

3. XML FEASIBILITY

At the last International Society for Analytical Cytology Conference¹², ISAC XX, there was significant resistance to the use of DICOM. Although, we believe that this resistance was based on a lack of information, it was obvious that this resistance will be difficult to overcome. However, there were examples of the utility of XML for flow cytometry data¹³ and a realization of the utility and virtually universal commercial support for XML. Therefore, for reasons of expediency, it will be necessary for some groups to express the textual part of FCS in XML rather than DICOM and to provide a means to translate between XML and DICOM. At this point, it must be emphasized, that any laboratory that has access to a DICOM based information system should use it and should, if possible, acquire its data directly in DICOM.

Even if a standard, such as XML, were to eventually coexist or replace DICOM, it should be based on DICOM objects and data types. Object oriented analysis is a very powerful component of present day software engineering. Any standard must describe the objects and provide methods for them including their storage and transmission. The simplest way to have two standards interoperate is to base them on the same objects and data types. Since DICOM includes all of the data types and most of the objects needed for Analytical Cytology data, the proposed design already described in terms of DICOM can be ported to other formats. The textual objects and their data types in DICOM can be mapped to XML. However the mapping of the large binary DICOM data types, such as visual light images and waveforms, to a textual format would result in an unacceptably large increase in size of the data. Therefore, the large DICOM binary data types should remain in DICOM format.

3.1. SCHEMAS

XML Schemas¹⁴ provide a means for defining the structure, content and semantics of XML instance documents. Instance documents can be documents or "streams of bytes sent between applications, as fields in a database record, or as collections of XML Infoset "Information Items"". Schemas allow groups or organizations to create classes of documents which include shared vocabularies, a common thesaurus. XML Schema has recently (October 2000) been advanced to Candidate Recommendation status. XML Schema has the very significant advantage that the language used to specify the Schema is XML itself. Schemas include the definitions of: Elements, Attributes, and Types. A type is a collection of constraints on element content and attribute values. A type may be either simple, for constraining atomic types or complex, for constraining elements which contain other elements, such as sequences.

Below is an attempt to translate DICOM data elements into a fragment of an XML Schema. The Registry of DICOM data elements in the Data Dictionary is a table with four fields: Name, Tag, Value Representation (VR), and Value Multiplicity (VM). The DICOM name maps to the XML element name. The Tag and VR are attributes each with a fixed (constant) value. The Value Multiplicity is handled by the XML minOccurs and maxOccurs constructs. The Tag is the unique value that identifies every DICOM data element. The Tag data type can be described:

```
<simpleType name="Tag_Type">
  <restriction base="string">
    <pattern value="[0-9a-fA-F]{4}, [0-9a-fA-F]{4}"/>
  </restriction>
</simpleType>
```

The DICOM Value Representations Table has the following fields: VR, Name, Definition, Character Repertoire, and Length of Value. The Value Representation is an enumerated type which includes a two letter abbreviation. It is the data type or class of the DICOM element. The VR type can be described:

```
<element name="Tag" type="d:Tag_Type"/>

<simpleType name="VR_type">
  <restriction base="string">
    <!--A few examples-->
    <enumeration value="AE"/> <!--Application Entity-->
    <enumeration value="AS"/> <!--Age String-->
    <enumeration value="AT"/> <!--Attribute Tag-->
```

```

<enumeration value="CS"/> <!--Code String-->
<enumeration value="DS"/> <!--Decimal String-->
<enumeration value="DT"/> <!--Date Time-->
</restriction>
</simpleType>

```

DICOM Number of Waveform Channels Type, can be described:

```

<complexType name="Num_Waveform_Channels_Type">
  <sequence>
    <element name="Number" type="unsignedShort"/>
  </sequence>
  <attribute name="Tag" type="d:Tag_Type"
    use="fixed" value="003A,0005"/>
    <!--The d: identifies that this type was created in this Schema-->
  <attribute name="VR" type="d:VR_Type"
    use="fixed" value="US"/>
</complexType>

```

Finally the Number of Waveform Channels element can be described:

```

<element name="Num_Waveform_Channels"
  type="d:Num_Waveform_Channels_Type"
  minOccurs="1" maxOccurs="1"/>
  <!--Its Value Multiplicity equals 1; and it is required-->

```

The use of an attributes with a fixed value eliminates the need to enter a value into the Web page; yet, permits the value to be accessed by the application.

4. Conclusions

There is no need to maintain a unique standard for Flow Cytometry, since it is now possible to express all of the FCS keywords that are used to describe a Flow Cytometry experiment in DICOM. The use of DICOM provides a rich source of data elements that can be used to augment the present FCS information into clinically useful information that is compatible with current medical imaging and information systems. Flow Cytometry and Automated-Stage Microscopy are sufficiently similar that they should employ the same laboratory informatics standard, DICOM. DICOM by separating the list-mode array into a separate file and incorporating the cell type data into an index provides a simpler and easier to maintain structure than the FCS monolithic structure.

Clinical laboratories that have a DICOM infrastructure would benefit from transforming their Analytical Cytology data into DICOM. At present, XML can in principle be used for limited purposes provided that the data is in a DICOM compatible format. XML has the severe limitations of not including means to precisely control image output devices, such as monitors and printers, and does not include the equivalent of the standardized DICOM binary formats and services.

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