SIEMENS

AVT
AVT2EXT

[redacted] SCR

Algorithm Validation Toolkit

Requirement Specification

Version 1.0

Last Change: 2010-05-10

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SCR-SAP

History

Document History

Version/ Status	Date of Issue	Author	Change and Reason of Change / Change Request/CHARM
0.1	2009-11-04	Robert W. Schwanke	First draft, with review by Scott, Jie, Fabian, and Christophe
0.2	2009-11-16	Robert W. Schwanke	Backlog requirements added and AE requirements revised based on discussions.
0.3	2010-01-29	Robert W. Schwanke	Adjusted requirements after meetings with Nick Petrick of CDRH in December2009. Consistent with FS r03
1.0	2010-05-10	Robert W. Schwanke	Released version.for AVT2EXT delivery

History of released Versions

Version	Release date	Product Version
1.0	2010-05-10	AVT2EXT

Table of Contents

1 Introduction

1.1 Purpose of the document

The purpose of this document is to document the use cases and, requirements, for the software package “Algorithm Validation Toolkit”, version “AVT2EXT”.

1.2 Definitions and abbreviations

See *AVT2EXT Definitions and Abbreviations*, a separate document.

1.3 References

[1] Medical Software from SCR, SW Quality Management Plan, 1010001 EQP 01S 01, SCR.

[2] SCR’s Med Projects QM-System, SCR, http://intra.scr.siemens.com/QM/scrsMedQhomepage.htm

[3] Standard Software Process, Directive 4.2.1.d-D01, R6.0, 14 Nov 2007, SCR.

[4] AVT2EXT SPMP 0.5.5.

[5] AVT Functional Specification 1.0.

[6] WHO handbook. *WHO handbook for reporting results of cancer treatment.* Offset Publication No. 48. Geneva (Switzerland): World Health Organization; 1979.

2 General description

2.1 Product goal

2.1.1 Product name and version

AVT2EXT

2.1.2 Goal statement

See *AVT2EXT Vision, Scope, and Technical Overview.*

2.1.3 Product drivers

The eventual products emanating from this and later project stages are envisioned to support the following research interests:

- Facilitate data and software sharing between imaging measurement researchers in the caBIG community.
- Facilitate algorithm experiments on large numbers of patient images.
- Facilitate research in manual and semi-automated measurement techniques by providing a toolkit for building experiment-specific, protocol-controlled image reading tools.

2.2 Product profile

2.2.1 Intended use

These software tools are intended for further programming and use by researchers exploring the statistical validity of medical image measurement techniques and their effectiveness as biomarkers for patient conditions in cancer care.

2.2.2 Patient groups

AVT is not intended for use with patients, but only with de-identified images.

That being said, images studied so far have included liver tumors, Glioblastoma multiformes, and thoracic phantom tumors.

2.2.3 User classes

In the long term, AVT will support the following user classes:

- Experimenter: Uses AVT to analyze the variability of annotations for some research project.
- Annotator: Uses the Image Reader to examine and annotate studies for some research project.
- Developer: Customizes AVT to the needs of a research project.
- Installer: Installs AVT for use by experimenters and developers.

Note: the following user class is ***not*** supported:

- Clinician: There is no "Clinician" user class, since this AVT2 Application is not intended, and is specifically forbidden, to be used for clinical purposes.

In the AVT2EXT development cycle, the role of the Developer is practiced only within the AVT team. Other developers are not supported in this release. The documentation delivered at the end of the cycle will include some information that is helpful to future Developers.

2.2.4 Operation conditions

AVT operates on standard computer workstations in research settings.

2.2.5 System environment

Although AVT is intended to be platform independent, it has only been tested and documented for use on Windows XP.

The following prerequisites are necessary in order to install and run AVT.

- Java 6 SDK preferably jdk1.6.0_10 or later, 32 bit version, from [1]
- R Statistical Package preferably R 2.8.0 from [2]
- Graphics card supporting OpenGL 2.0 with hardware shaders
- Minimum 1280x1024 pixel display
- 256MB graphics memory required (512MB preferred)
- When the platform OS is Windows XP, the Windows Classic user interface coloring theme is strongly recommended.

2.2.6 Version scope

The current version AVT2EXT) is intended to handle experiments on 55 specific thoracic phantom images collected by the FDA CDRH (Center for Devices and Radiological Health). It has not been tested on other types of images.

The TCGA version was intended to handle markup of certain specific Glioblastoma Multiforme studies collected in the NBIA under the collection called “TCGA”.

Version 2 was intended to handle experiments on 10 specific liver tumor studies from the MICCAI ’08 Grand Challenge data collection.

2.3 General limitations

Not for clinical use.

2.3.1 Data Input/Output

Diversity of DICOM usage in industry and medicine creates some types of DICOM studies to which AVT cannot yet be applied. Although DICOM is a “standard”, there are so many variants in how DICOM is used by medical imaging manufacturers and radiology departments that no general assurance can be given to handle all kinds of DICOM CT and MR images. Therefore, each new project that uses AVT must begin with testing to determine whether the types of images to be analyzed have new characteristics that AVT cannot yet handle. AVT can be readily extended to handle such new characteristics, but it cannot be warranted in advance to handle all of them – there are too many!

The immaturity of AIM forces AVT to extend it and to use it in non-standard ways. . All such variances are undertaken cautiously and in consultation with the AIM development team.

2.3.2 Software interfaces

AVT is a set of applications hosted by XIPHost, a separate caBIG IVI product. All of AVT’s connection to caGRID are mediated by XIPHost in this release. These connections are used to import and export DICOM and AIM data.

2.3.3 User interfaces

AVT provides four user interfaces:

- Database Query interface, embedded in XIPHost, for selectingselected data to analyze from the AVT Assessment Database.
- Image Reader interface, for annotation and markup of images.
- Algorithm Execution user interface, for initiating and monitoring the execution of algorithm experiments.
- Measurement Variability Tool user interface, for exploring the statistical properties of AIM data.

2.3.4 Hardware interfaces

Minimum 1280x1024 screen, supported by OpenGL2.0 with hardware shaders.

2.3.5 Operating system

Designed to be platform-independent, but only tested only on Windows XP.

2.3.6 Programming language

C++, Java, OpenInventor, and R.

2.3.7 Out of scope

This section lists high-level topics that were considered for inclusion but ultimately rejected as out of scope. Specific requirements or use-cases that are considered useful and can be considered for implementation in future cycles are marked as "deferred" elsewhere in this document, not "out of scope".

2.3.7.1 Debugging interfaces

AVT has several debugging interfaces that future users may find useful, such as an interface to save an AIM object directly to disk without going through the WG-23 return parameter interface. These interfaces, though useful, are not supported.

2.3.7.2 Incidental data handling programs

AVT has several incidental scripts, such as a small program to load a set of AIM annotations from folders into AD, that were written quickly as placeholders for future functionality. These programs are not part of the AVT product per se, and hence there is no commitment to them being of "operational pilot" quality.

3 Requirements

3.1 Miscellaneous

MISC_IA_clinical_use_disclaimer

The Image Reader shall warn the user, before displaying any images, that the Image Reader is not approved for clinical use, and capture an acknowledgement from the user indicating that s/he understands this.

MISC_open_source

AVT shall be implemented entirely with open-source software, except for the database engine used in AD, for which the IMAG working group has granted an exception allowing it to use IBM's DB2 Express C.

DEFER
MISC_grid_connectivity
(Not required specifically for AVT2EXT)

Although not technically required for AVT2EXT, we should deliver this functionality if we have the opportunity to do so; otherwise we risk causing our customer anxiety.[1]

MISC_grid_connectivity DEFERRED

AVT shall be a caGrid client, connected to the grid via XIPHost.

XIPHost_default_working_directories

The AVT installation shall automatically create and configure the working directories of XIPHost.

MISC_operational_pilot

IA, AE, and the Audit Trail functionality shall be delivered with the quality of an operational pilot, as defined in the .Statement of Work.

3.2 Data Types

DEFER
DATA_DICOM_image_types
(For AVT2EXT we are only supporting a specified list of images.)

DATA_DICOM_image_types DEFERRED

AVT shall handle (e.g. load, display, and analyze) DICOM images that have the following characteristics: no multiframe, no tiled data, no compressed data, up to 400MB overall dataset size, phantom materials that approximate the real density of lungs, bones, tissue,

[1] Italics below requirement descriptions contain discussion material that is intended to remain after review comments have been resolved and removed.

and air, and tumors that are +100HU or -10HU.

DATA_thoracic_phantom_images

AVT shall handle (e.g. load, display, and analyze) each of a designated subset (Petrick's "Pilot 15" and "Pivotal 40") of the thoracic phantom images that are available from NBIA. These images contain up to 6 phantom tumors in each half of a phantom thorax, with ground truth location and numerical volume. There are four different tumor shapes, each with a nominal radius of 10mm. Two of the shapes also come in a larger size: 20mm radius.

DATA_thoracic_phantom_tumor_AIM_object

A Thoracic phantom tumor AIM object shall include the following (each item is optional in any given instance of the object):

- Independent variables describing the image that was or will be annotated, but which are not DICOM attributes, such as the ordinal exposure sequence number (first or second) that distinguishes two otherwise-identical DICOM series.
- The identity and related information about the human that created the annotation.
- The identity, version, parameters, and related information about the algorithm that created parts of the annotation.
- A reference to the seed AIM object used as input to the algorithm or reading session that created parts of the annotation.
- A label for the tumor, unique among tumors in the same phantom configuration
- Graphical markup showing RECIST diameter of the tumor on a slice
- Numerical RECIST diameter of the tumor.
- Seed line segment, interior to the tumor on a slice
- An indication of whether or not the AIM object is a seed annotation.
- Graphical markup showing two orthogonal diameters of the tumor on an original slice (as defined in WHO standard [6])
- Numerical length of two WHO diameters, and their WHO product.
- Volume segmentation of a tumor, represented as a reference to a DICOM segmentation object.
- Numerical volume of a tumor
- Numerical density of the tumor
- One or more contours on each slice of the series, up to a TBD maximum numbers of contours per slice and TBD contours per annotation.

  This bulleted item is not required for AVT2EXT, but will be required later.

  A single oddly-shaped tumor can intersect a slice in two or more disjoint regions. We need to discuss whether AVT needs to store and display the contours themselves, or only reconstruct them on the fly from the probability map.

  The CMIV team should suggest practical values for the TBD numbers above.
- Symbolic annotations describing the tumor, constrained by a standard vocabulary.

  This requirement is independent of which vocabularies are used.

- Calculations derived from the above, according to the needs of the Thoracic Phantom case study, including volume and diameters, which need to be distinguished as having been calculated from the volume instead of being markups. AIM has a representation for calculations.

DATA_CDRH_annotation_import

The AVT team shall import CDRH annotation files from proprietary textual and/or XML formats into AIM format. Any conversion software written for this purpose is not a delivery of the project.

DATA_load_and_display_AIM_annotations

AVT shall load and display previously-stored AIM annotations of Thoracic Phantom images. AVT is permitted to ignore any information in the AIM object that is not specified in the requirement "**DATA_thoracic_phantom_tumor_AIM_object**" (defined above). If not ignored, the information should be displayed sensibly.

DATA_seed_AIM_object

AVT shall import and export seed AIM objects, store them in AD, and use them in applications. A seed AIM object contains an attribute indicating that it is a seed and a markup indicating the location of a tumor (typically, the graphic markup is located entirely inside the tumor).

XIPHOST_query_seeds

XIPHost shall support queries for AIM objects from AD that are restricted based on the value of the "seed" attribute of AIM objects.

DATA_meaningful_AIM_file_name DISCUSSING

IA and AE shall generate AIM file names that are meaningful as well as likely to be unique.

Tracker #2326, originating from Justin Kirby

Assignee: None

The file name will likely contain the patient name and a timestamp.

DEFER
AD_multi_value_XML_fields

(For advanced queries, later.)

"We probably need multi-valued fields to handle ImagingObservationCharacteristics that could appear several times in an AIM annotation. Querying for an attribute in this structure would still be done specifying a single value and all AIM files matching at least one tag with this value would match the query. If we need to search on them, a normal table approach won't work. We could combine multiple values into concatenated strings and allow substring search.""

Tracker #1041.

Assignee: None (should be Fabian).

Comment: 16h work

AD_multi_value_XML_fields DEFERRED

AD shall support multi-value XML fields.

DEFER
AD_multiple_collections

(Needed for scalable databases, later.)

Lacking this feature interferes with demos and testing, as well as, in the long term, the end user convenience. There are different levels of implementation. Non-overlapping collections could be implemented by adding a single column to the image table but overlapping collections are more complicated. Another idea was to use AIM annotations to group images into collections but this will induce the need to distinguish between different types of AIM annotations (collections, actual image markups) which may already be needed for seed annotations. This is not useful without the next.

Tracker #1107

Assignee: None

AD_multiple_collections DEFERRED

AD shall represent the concept of a collection associated with an experiment, such that a single database can store multiple collections and a user can restrict queries to the collection(s) he is interested in.

DEFER
AD_curation_operations

(Waiting to re-architect with respect to XPHost)

See [[Collections_Design]] and [[AVT_Front-End_Design:_XIPHost_and_More]]in the wiki for possible design. This is very expensive. While AD is currently a backend library this would require the development of a user interface for AD.

Tracker #1107

Assignee: None

AD_curation_operations DEFERRED

AVT shall provide a user interface for curating collections of cases, including operations such as creating and deleting collections, adding and removing cases, designating ground truth and seed annotations.

3.3 Viewport

VIEW_double_oblique_MPR_viewing

AVT shall display 3D CT and MRI image series (specified in other requirements) in a double-oblique 3D-MPR viewer.

VIEW_text_overlay

The AVT viewports shall include a text overlay with image header information appropriate to the Thoracic Phantom images, including Patient info (age, gender, name), institution, scan parameters, and window/level, (consistent with Siemens best practice).

VIEW_orientation_cube

AVT viewports shall show an orientation cube in each view indicating the direction of view, based on model matrix, (consistent with Siemens best practice).

DEFER
VIEW_scale

(not required for CDRH case study)

VIEW_scale

The AVT Viewports shall show a scale in each pane indicating the dimensions of the image correspond to the physical dimensions of the imaged tissue, based on model matrix, (consistent with Siemens best practice).

VIEW_CT_window_and_level_settings

The AVT Viewports shall initialize the window and level settings from DICOM header information for CT datasets, (consistent with Siemens best practice).

VIEW_window_and_level_presets

The AVT Viewports shall provide tools to select window and level settings according to the modality of the image and the portion of the body being viewed, (consistent with Siemens best practice).

DEFER
VIEW_phantom_presets

(Using lung presets for CDRH case study)

VIEW_phantom_presets

The AVT Viewports shall provide tools to select window and level settings suitable for comfortable viewing of thoracic phantom images.

VIEW_window_and_level_adjustment

The AVT Viewports shall provide a tool to adjust the window and level settings by depressing the middle mouse button and moving the mouse, and normalize its sensitivity according to the range of meaningful values for the image being displayed, (consistent with Siemens best practice).

DEFER
VIEW_MR_auto_windowing

(We don't have any MR images in our case studies yet.)

VIEW_MR_auto_windowing DEFERRED

The AVT Viewports shall initialize the window and level settings by auto-windowing for MR datasets, (consistent with Siemens best practice).

VIEW_pan_zoom

The AVT Viewports shall include a tool to pan and zoom the image, (consistent with

Siemens best practice).

VIEW_mouse_cursor_feedback_on_adjustment_tools

The AVT Viewports shall switch between different mouse cursor icons to indicate whether the currently-active adjustment tool is pan, zoom, window/level, or none of these, (consistent with Siemens best practice).

IA_dynamic_viewport_layout

IA shall provide three alternative viewport layouts (2x2, 3+1, 1x1)

DEFER
MVT_viewport_layout

(Not required for CDRH case study)

The fixed layout actually implemented is apparently sufficient.

MVT_viewport_layout

MVT shall display markups in a 1x3 3D-MPR viewport layout (without fused data display).

VIEW_volume_segmentation_display_as_contours_on_slices

The AVT Viewports shall display volume segmentations as contours on the original slices in 3D-MPR displays.

VIEW_volume_segmentation_display_on_alternate_planes

The Image Reader shall display volume segmentations as contours on all three views of the 3D MPR display.(only the contour in the original slice view shall be editable.)

VIEW_fused_volume_rendering

The AVT Viewports shall provide a fused volume rendering of one tumor segmentation at a time, with volume rendering of the surrounding tissue fused with unshaded surface display of the tumor.

VIEW_multiple_read_only_markups

The AVT 3D-MPR Viewports shall be capable of displaying multiple read-only markups of the same image concurrently, up to a TBD maximum number of concurrent markups. (In AVT2EXT the defined maximum is 3, but that may change later.)

This viewport capability is not required in the Image Reader in AVT2EXT, but may be in the future. Therefore, the requirement key begins with "VIEW" rather than "MVT", so that it won't have to change later.

3.4 Segmentation and Diameters

SEG_automatic_3D_volume_segmentation

AVT shall automatically segment a tumor, given a seed (point or stroke) located on an original slice image of the tumor.

SEG_ITK_volume_segmentation_algorithm

AVT shall use a seed-based volume segmentation algorithm based on Watershed + Fast

Marching techniques, using Itk components. (The algorithm shall be of ordinary quality.)

SEG_IA_mark_tumor_with_seed

IA shall provide a tool to indicate the location of a tumor by drawing a seed point or stroke in a viewport. (For algorithms that start from a single point, the mid-point of the stroke shall be used as the seed.)

SEG_IA_invoke_automatic_volume_segmentation

IA shall provide a command to invoke the 3D volume segmentation algorithm to segment the tumor indicated by the currently-displayed seed.

SEG_IA_manual_3D_volume_segmentation

The Image Reader shall provide tools to manually segment a 3D volume by drawing contours on the original slices in a 3D image.

SEG_IA_edit_volume_segmentation_contours

The Image Reader shall provide tools to edit the contours of a volume segmentation manually, by drawing new closed contours that are added to or subtracted from the existing contour.

SEG_IA_manual_diameter_on_a_2D_slice

The Image reader shall provide a manual tool to measure the diameter of a tumor image on an original slice, (consistent with the definition of the diameter of a tumor in the RECIST standard).

SEG_IA_manual_orthogonal_diameters_on_a_2D_slice

The Image Reader shall provide a tool to measure two orthogonal diameters of a tumor image on an original slice, (consistent with the standard definition of WHO diameters).

DEFER
SEG_diameter_calculations_from_volume_segmentation
(Not required for CDRH case study)

SEG_diameter_calculations_from_volume_segmentation

The Image Reader shall calculate the maximum on-slice diameter and maximum on-slice orthogonal diameters of a 3D volume segmentation, (consistent with RECIST and WHO standards).

DEFER
IA_template_driven_symbolic_annotation
(Not required for CDRH case study)

This functionality was prototyped in TCGA Reader and will be required in the future, but is not required for CDRH case study.

IA_template_driven_symbolic_annotation DEFERRED

The Image Reader shall capture symbolic annotations in a UI that is configurable by a template.

This will be similar to the template used in the TCGA Reader.

3.5 Image Reader

See unsettled point, "Image Reader" vs. "Image Annotation"

IA_SoV_case_study

The Image Reader shall provide the image viewing and annotation features needed to implement the Sources of Variation (SoV) Case Study on Thoracic Phantom image data, as specified in other requirements.

IA_multiple_AIM_annotations_per_image_reader_session

The Image Reader shall manage (load, store, create, edit, and/or display) multiple AIM objects associated with the same Series during a single Image Reader session Only one AIM object shall be actively edited at a time.

The CMIV team should suggest practical values for the TBD numbers above.

IA_store_annotations

The image reader shall store annotations persistently in AIM format via the WG23 application hosting interface.

IA_store_pan_zoom_window_level

The image reader shall provide means to store pan, zoom, window, and level settings along with markups, such that when the markups are re-displayed later, they can be displayed with the same settings that were used when the markup was created.

IA_store_seed_annotations

The image reader shall save annotations suitably marked as seed AIM objects for use in Algorithm Execution.

IA_navigate_to_markup

The image reader shall provide a command to navigate to the currently-selected annotation's associated markup, including setting the window, level and zoom controls to the values they had when the annotation's markup was created.

IA_save_warnings

IA shall warn the user before exiting with unsaved user inputs and before saving the "same" annotation more than once.

Tracker #764, #838

MVT_null_calculation_warning

MVT shall warn the user who requests a calculation when all cases have been excluded from the analysis.

IA_label_confidence_scale_from_RadLex

Where IA collects confidence ratings on annotations, it shall label the confidence scale with RadLex terms for Uncertainty (RID29).

The confidence scale is not needed for CDRH case study, but remains in the Liver

Tumor Study.

DEFER
IA_compare_multiple_AIM_objects_concurrently
(Not required for CDRH case study)

Not needed for CDRH case study, but will be used in adjudicator applications.

IA_compare_multiple_AIM_objects_concurrently Deferred

The image reader shall display multiple previously-created AIM objects concurrently, for the purpose of comparing them, including only graphic annotation information and not symbolic information, up to a TBD maximum number of concurrently-displayed AIM objects. (For AVT2EXT the defined maximum number is currently 3, but that might change later.)

When we do implement this functionality, we need to decide what to do about the fused volume rendering view. One solution is to render multiple markups there as well. Another is to switch to a different layout, similar to the one in TCGA0.4, where there are only 3 views instead of 4.

3.6 Algorithm Execution

AE_batch_segmentation

AE shall apply a segmentation algorithm to a batch of images of tumors without user interaction once the batch has been submitted to AE.

AE_WG23_hosted_application

AE shall be a WG23 hosted application, invoked from XIPHost.

AE_input_cases

AE shall accept a batch specification in the form of a set of seed AIM objects and their associated series, passed to it via its WG-23 interface.

AE_algorithm_Plug_in_Interface

AE shall expose an algorithm plug-in interface, in which the algorithm is a scene graph component.

DEFER
AE_batch_size_1000
(Requires improved architecture)

The number "1,000" comes from the Thoracic Phantom case study, which does indeed have 1,000 cases. This requirement is deferred because we know that handling a thousand cases efficiently will require an architecture that controls the distribution of data and processing elements across multiple processors, machines, and geographical locations. The AVT2EXT funding is not sufficient to develop that capability.

AE_batch_size_1000 DEFERRED

AE shall be designed to process large batches (for example, a thousand) of cases; however, for AVT2EXT, demonstrating it on a batch size of 10 or greater is a sufficient

test.

AE_progress_indicator

AE shall display a progress indicator that changes appearance at least once per case processed.

AE_store_results

AE shall store the results of the segmentation algorithm as AIM objects, one per segmentation, each including a reference to the seed AIM object used as the starting point for the segmentation algorithm.

AE_cancellation

AE shall provide an interface by which the user can abnormally terminate the batch processing within a reasonable time.

AE_results_summary

AE shall summarize the batch execution results in a simple UI report to the user listing the number of annotations created and the time needed for processing.

3.7 Measurement Variability Tool

MVT_SoV_case_study

MVT shall provide the data handling and statistical features needed to implement the Sources of Variation (SoV) Use Case on Thoracic Phantom image data, as detailed in other requirements.

MVT_CDRH_case_capacity

MVT shall have sufficient capacity to analyze a data collection involving up to fifty cases, which is the size of the CDRH “Pivotal 40” collection. (A case is all the data surrounding one image of one tumor.)

MVT_CDRH_annotation_capacity

MVT shall have sufficient capacity to analyze data collections containing up to 1500 annotations, which is the size of the CDRH “Pivotal 40” collection.

MVT_independent_variables

MVT shall support analysis of the following independent variables:

- CT Acquisition parameters: Exposure intensity, Pitch, Collimation, Slice Thickness, Reconstruction Kernel
- Reader identity
- Exposure repetition (an ordinal number)
- Nodule shape and placement

  E.g. attached, unattached, spherical, elliptical, lobulated, spiculated, random
- Nodule Density
- Tool used for markup
- The version of the segmentation algorithm

DEFER
MVT_independent_variables_future

(Not required for CDRH case study)

MVT_independent_variables_future DEFERRED

MVT shall be able to process but ignore the following independent variables, present in the AIM data, which may be needed in future experiments:

- Scanner model,
- Exposure intensity (in mAs)
- Tube Voltage,
- Collimation
- ID of Reconstruction Kernel
- Slice overlap
- Pitch
- Nodule anatomical location

MVT_suppress_irrelevant_variables

MVT shall not mention, in its interfaces, specific variables that are irrelevant to the study at hand, such as age and gender for phantoms.

MVT_inter_reader_variation

MVT shall support inter-reader variation analysis with up to 6 different readers, some of which might be algorithms. The design shall not contain any intrinsic limits on the number of readers it can handle.

MVT_intra_reader_variation

MVT shall support intra-reader variation analysis with up to 3 different time points. The design shall not contain any intrinsic limits on the number of time points it can handle.

DEFER
MVT_partitioning_by_values

(Not required for CDRH case study)

MVT_partitioning_by_values

MVT shall support statistical analysis that partitions the data according to the values of supported independent variables

MVT_ground_truth_reader

MVT shall provide the means to designate ground truth by the name of the reader whose annotations are to be treated as ground truth.

MVT_variable_selection

MVT shall provide the means for the user to choose variables for certain kinds of statistical analysis (e.g. ANOVA), interactively, for example by checking boxes in a list.

DEFER
MVT_t_test
(Not needed for CDRH study)

MVT_t_test

MVT shall support statistical analysis by means of the t-test

MVT_one_way_ANOVA_methods

MVT shall support statistical analysis by means of one-way ANOVA methods.

MVT_factorial_ANOVA_methods

MVT shall support statistical analysis by means of factorial ANOVA methods

MVT_multiple_regression

MVT shall support multiple regression analysis

DEFER
MVT_mixed_effects
(insufficiently clear requirements for CDRH study)

MVT_mixed_effects

MVT shall support mixed effects models

DEFER
MVT_Levene_test
(Not needed for CDRH study)

MVT_Levene_test DEFERRED

MVT shall support Levene's test for the homogeneity of variances.

MVT_existing_summary_statistics

MVT shall continue to support the summary statistics of Bias, mean error, standard deviation, and coefficient of variation

MVT_histogram_charts

MVT shall support graphical analysis by means of histogram charts

DEFER
MVT_box_and_whisker_charts
(Not needed for CDRH study)

MVT_box_and_whisker_charts

MVT shall support graphical analysis by means of Box Plots.

MVT_MPR_markup_comparisons

MVT shall support comparison of alternative markups of the same tumor by displaying 2 alternative diameters or volume segmentations of the same series, overlaid simultaneously on the same MPR display of that series.

MVT_list_original_measurements CHEAP

MVT shall provide options to list the original measurements in the calculations table, including RECIST and WHO diameters and volume, when available.

MVT_error_difference_measures

MVT shall provide the means to display and analyze the following error and difference measures (where the square brackets are used to indicate different variations of the same basic measure):

- [Relative] RECIST error [magnitude]
- [Relative] WHO error [magnitude]
- [Relative] Volume error [magnitude]
- Avg surface distance error
- RMS surface distance error
- Max surface distance error
- Volume overlap ratio

MVT_exclude_individual_cases

MVT shall provide the means for the user to exclude individually-selected cases and annotations from its analysis (for example, by un-checking a check box).

DEFER

MVT_statistics_selector_panel

(Deferred out of expediency)

Deferred out of expediency, since it is a usability improvement, not an essential function.

MVT_statistics_selector_panel DEFERRED

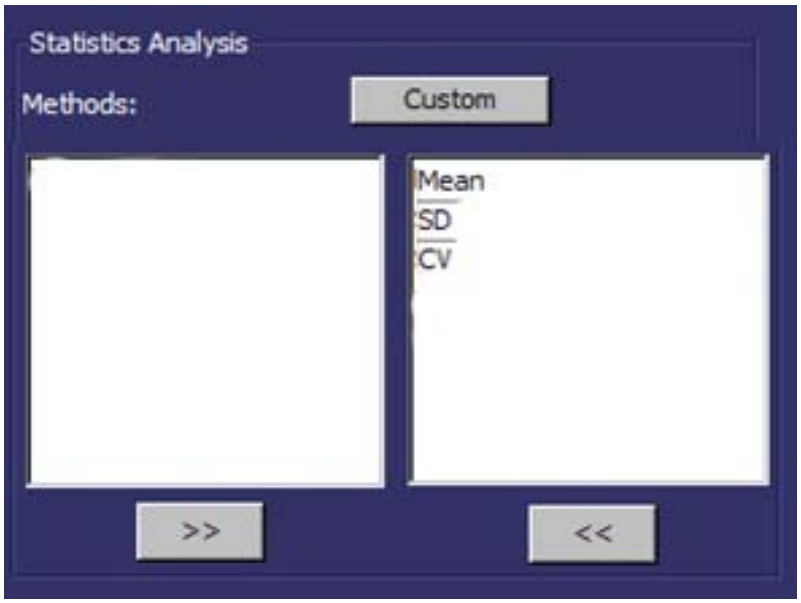
The UI for selecting statistics should use controls that look like <<, >>, and **new** from the calculation selector screen. The summary statistics shall always be computed on all columns, eliminating the UI piece that chooses which column to compute it on.

Tracker #752

Assignee: Zheng

See Unsettled Point "Statistics Selector Panel"

Example (mockup)



HOST_query_all_experimental_variables

XIPHost shall provide query capability to specify values for all of the independent variables and annotation types involved in the experiment, whether they are DICOM or AIM fields.

MVT_outliers_SD

MVT shall support outlier cutoffs scaled by the standard deviation (SD) of the values being examined.

MVT_outliers_IQR

MVT shall support outlier cutoffs scaled by the inter-quartile range (IQR) of the values being examined.

MVT_highlight_outliers

MVT shall highlight numerical outliers in data tables, for example with color. (The outliers are already identified by user-specified statistical criteria.)

DEFER
MVT_statistic_analysis_report

(Not required for CDRH study.)

MVT_statistic_analysis_report DEFERRED

MVT shall provide a simple statistic report for exporting the analysis results in HTML or PDF format.

MVT_export_plots

MVT shall provide the means to export each of its plots for use in documents.

DEFER
MVT_export_documents
(Not required for CDRH study.)

MVT_export_documents DEFERRED

MVT shall provide the means to export each of its analyses for use in documents.

DEFER
MVT_export_data
(Not required for CDRH study.)

MVT_export_data DEFERRED

MVT shall provide the means to export all of its internal data for further analysis in Excel and R.

3.8 Audit Trail

AUDIT_create_annotation

AVT shall create an audit trail entry each time an annotation is saved to the AD.

AUDIT_comments

AVT shall capture optional user comments in audit trail entries at the time the entries are created including but not limited to the means by which ground truth was established and the user's subjective estimate of the uncertainty of an annotation.

DEFER
AUDIT_user_role
(There seems to be only one user role in the CDRH study.)

AUDIT_user_role

AVT shall capture the user's identity and role in audit trail entries.

See Unsettled Point, "Capturing the User's Role".

AUDIT_image_reader

The Image Reader shall implement all of the Audit requirements that are relevant to interactive image reading, specifically **AUDIT_create_annotation**, **AUDIT_comments**, **AUDIT_user_role**, **AUDIT_algorithm_name_and_version**, and **AUDIT_AVT_version_date_and_time.**

AUDIT_algorithm_execution

The Algorithm Execution Tool shall implement all of the Audit requirements that are relevant to batch execution of image segmentation algorithms, specifically **AUDIT_create_annotation**, **AUDIT_user_role**, **AUDIT_algorithm_name_and_version**, and **AUDIT_AVT_version_date_and_time.**

AUDIT_algorithm_name_and_version

AE shall record the algorithm identification and version number in audit trail entries each time it creates an annotation.

AUDIT_AVT_version_date_and_time

AD shall record audit trail information supplied by IA and AE and in addition record the version of AVT and the date and time of the entry.

3.9 Installation Package

INSTALL_release_notes

The installation package shall contain release notes including known bugs and their status, and provide references/links to other relevant documentation.

INSTALL_binary_code

The installation package shall include the binary code for AVT, including AE, IA, MVT, and AD.

INSTALL_source_code

The installation package shall include source code with adequate commenting (according to criteria to be determined by the AVT team).

INSTALL_installation_procedure

The installation package shall include a document describing the installation procedure.

INSTALL_end_user_scenario_documentation

The installation package shall include step-by-step instructions for using AVT to carry out an example scenario for each of the use cases documented in the Functional Specification.

INSTALL_end_user_feature_documentation

The installation package shall include step-by-step instructions for using AVT to exercise each of its required functional features.

3.10 XIPHost

HOST_query_exclude_series

XIPHost shall provide the capability to query for a set of AIM objects based in part on the DICOM series they describe, and then invoke an application by sending it only the AIM objects and their associated DICOM segmentation objects, without also sending the DICOM series themselves.

4 Unsettled points

4.1 DICOM Image Types

Do we need a separate requirement spelling out the characteristics of the DICOM Series types that we can handle? Some say we should only specify the Thoracic Phantoms, but even there we should not promise to handle all 1,000 images that Nick Petrick has collected. See section 3.2 Data Types.

4.2 Seed Annotations

We have decided to distinguish seed AIMs from result AIMs by the type field in the root class of the AIM object.

4.3 Statistics Selector Panel

DEFERRED

Is there any value to allowing the user to select which columns a summary statistic calculation is applied to? Is that value enough to warrant the extra screen space needed by the older UI, vs. the simplification suggested under requirement “MVT_statistics_selector_panel”?

4.4 Capturing the User’s Role

DEFERRED

We disagree on whether the Image Reader should contain a user interface for capturing the user’s role. In the short term, there may only be one such user role, so it may not be worth capturing. However, in real clinical trials there are many roles, and AIM provides a representation for recording which role the reader is playing.

4.5 Storing Contours vs. Converting to Segmentations

DEFERRED.

The TCGA Radiology project required IA to store contours, since we were not using them for segmentation. Bob believes that some research applications of AVT will explore different algorithms for converting hand-drawn contours into segmentations, and will therefore need to store the hand-drawn contours themselves, in addition to the segmentations resulting from algorithmic conversion. Jie has so far rejected this concept, perhaps due to the other issues surrounding contours and display of contours.

4.6 “Image Reader” vs. “Image Annotation”

Can we systematically rename the IA tool, “Image Reader”?

See “Image Reader” section of requirements.

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