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A Universal Solution to Automated Compliance Verification for Clinical Trials

Yulong Yan, PhD[1]; Robert Timmerman, MD[1]
[1]Department of Radiation Oncology University of Texas Southwestern Medical Center

ABSTRACT

Purpose: Clinical trials require the extraction of specific metrics from DICOM plan datasets for protocol-driven data analysis. Because these metrics vary widely across trials, it has been difficult to develop an automated system capable of supporting diverse study requirements. This study proposes a methodology and system architecture that enable universal, automated compliance verification across a broad range of clinical trials.

Methods: We designed a compact but comprehensive library of forty-seven commonly used metrics, most parameterized by a variable x. To improve interpretability and flexibility, internal metric symbols are formed using two prefixes and eight suffixes, which define how data is extracted and what elements are evaluated. Users can create custom metric labels for exported records in standardized formats. Each metric can be paired with one of seven comparison operators to evaluate extracted values against protocol-defined goals and tolerance limits. To extend functionality, the system supports user-defined variables and arithmetic expressions, enabling the calculation of derived metrics from primary measurements.

Results: The system has been successfully deployed in multiple internal and multi-institutional clinical trials. Data analysis follows a largely automated workflow: (1) construct a protocol template using the built-in protocol builder; (2) load a dataset and evaluate plan compliance using the template; and (3) generate printable and exportable review reports. To date, the system has accommodated all clinical trials encountered by the authors.

Conclusion: A universal automated solution for compliance verification in clinical trials is feasible. A concise, well-structured metric set combined with variables and arithmetic operations provides an effective and versatile foundation for broad clinical trial support.

CONTACT

Yulong Yan
Radiation Oncology, UT Southwestern
2280 Inwood Rd., Dallas, TX 75390
Email: yulong.yan@utsouthwestern.edu
Phone: (214) 645 7636

INTRODUCTION

Clinical trials are designed to evaluate how variables, represented by metrics, affect outcomes. The sets of metrics specified in trial protocols can vary drastically depending on studies' objectives. This variability has made it challenging for researchers to develop a universal automated system that is capable of handling compliance verifications across diverse clinical trials. This study aims to propose a universal method and system to address this challenge.

METHODS AND MATERIALS

A system was developed to analyze plan datasets of clinical trials. There are three components in the system:

1. DICOM data parsing and articulation
2. Dose summation and DVH calculation
3. A set of predefined metric notions
4. A tool to create protocol templates
5. A module to automatically retrieve metric values from plan datasets based on protocol templates
6. A module to parse arithmetic expressions to compute derived metrices
7. A reporting module

47 metric notions (Table 1) was devised based on our experiences from clinical trials conducted over the past 10 years. To improve readability, two prefixes are used: "r" to denote a ratio or percentage, and "b" to denote a Boolean value (yes/no). In addition, nine suffixes are defined to further specify internal metric symbols (Table 2). To improve readability further and adapt to any naming convention for dose metrics, user-defined unique metric names are also added to model templates so that exported reports can be recognized by external data collection systems (fifth column in Figure 1). When a metric is not included in the defined set, it can be derived using an arithmetic expression(11th column in Figure 1), eliminating the need for manual intervention.

CF	CVx%	Dx%	bDmaxIn	HTCI	Rx	V	Vox%
CF%	rCVx	rDx	Dm	GI	Rx%	Vx	rVox
comm	rCVx%	rDx%	Dq1	IDL	Rx~	Vx%	rVox%
CI	date	Dmin	Dq3	iid	Rx%~	rVx	SI
CIx	Dp	Dmean	rDmax	nof	rvwr	rVx%	xx
CVx	Dx	Dmax	rDmax~	null	sid	Vox	

Table 1. The set of predefined metric notions. Take rVx as an example, if the variable x = 20, the notion becomes rV20, which means percentage volume receiving at least 20 Gy. For a metric not included in the table, a user-defined internal metric "xx" can be used for manual value entry.

RESULTS

The proposed system has been applied in multiple internal and multi-institutional clinical trials over the past decade. The data analysis workflow consists of three main steps:

1. Constructing a protocol template based on the trial protocol.
2. Collecting and analyzing plan datasets using the template
3. Generating review reports or database entry reports in specified formats.

The metric set can be further expanded through the use of variables and arithmetic expressions. For example, the Healthy Tissue Conformity Index (HTCI) is defined as the ratio of the volume portion of a target covered by the prescription dose (variable a) to the total body volume receiving the prescription dose (variable b). HTCI can therefore be calculated using the expression "=a/b" (Figure 2). More complex expressions can also be defined as needed, such as "=(a+b)/(c−d/2)×e×100".

%	Percentage	o	outside
m	Median	p	Prescription
min	Minimum	q1	Q1 of interquartile
max	Maximum	q3	Q3 of interquartile
maxIn	Maximum point inside		

Table 2. Nine suffices and their meanings. For example, rVox, where x = 56.7. The notion becomes rVo56.7 which means the ratio of the volume outside an ROI receiving at least 56.7 Gy over the ROI volume.

=	**Equal to**	**<**	**Smaller than**	**<>**	**In a range**	**i**	**Information**
/=	Not equal to	>	Larger than	><	Outside a range		

Table 3. Predefined operators in protocol templates.

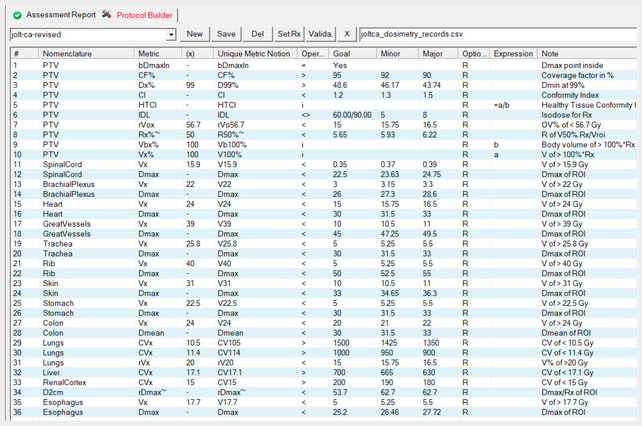

Figure 1. The tool to build protocol templates for \clinical trials.

DISCUSSION

There are so many ongoing clinical trials in the field of radiation oncology. The number of trials would be way larger if completed trials are revisited. So, there will be a large variety of metrics to deal with. It is quite challenging to devise a system that can model majority of if not all clinical trials. Based on our experiences on in-house or multicenter clinical trials in the last decade, a set of predefined 47 metrics can handle all we encountered trials. However, there are so many creative ways to look at clinical data when researchers are trying their best to find links between metrics and outcomes. So, it is very hard if not impossible to design a truly universal system that can model all trials in the future. There are three ways to expand the system:

1. Introduce arithmetic expression to calculate derived metrics based on predefined ones. It is included in this study.
2. Add user defined metric for manual input. It is also included in this study.
3. Expand the metric set. This requires system upgrades to accommodate more trials.

Based on our experiences, 1 and 2 have drastically enhanced our system. Arithmetic expressions are very powerful when it comes to automation and handling "unexpected" metrices.

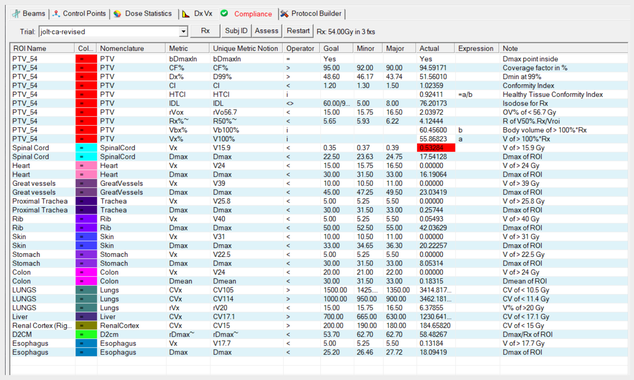

Figure 2. A sample compliance review report of a clinical trial. In the 11th column, V100% of PTV is defined as a, while Vb100% of PTV is defined as b, and the HTCI is defined as the expression "=a/b". The system will automatically calculate HTCI based on the expression.

CONCLUSIONS

Automated data analysis for clinical trials is both practical and effective. The incorporation of variables and arithmetic expressions significantly enhances the versatility of automated compliance verification systems, enabling broader applicability across diverse trial designs.

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