

What is claimed is:

1. A graphical user interface-based system for monitoring and guiding an ongoing clinical trial on an adjustable and real-time basis, comprising:
 - a. a clinical trial database for storing information from an ongoing clinical trial, wherein said information comprises a set of subject data that is being continuously updated as said ongoing clinical trial proceeds;
 - b. a boundary determination module for determining boundaries for a group of regions comprising a favorable region, a hopeful region and an undesirable region, wherein said boundaries are subject to boundary adjustment as said ongoing clinical trial proceeds, wherein each region represents a different level of risk associated with an accumulative effect of said ongoing clinical trial; and
 - c. a graphical user interface (GUI), operable with said boundary determination module, for displaying a plot of said accumulative effect of said ongoing clinical trial and displaying boundary parameters corresponding to said group of regions, wherein said GUI allows a user to adjust values of boundary parameters in view of said plot, thus generating new boundaries on a real-time basis as said ongoing clinical trial proceeds, wherein said accumulative effect of said ongoing clinical trial is continuously projected onto said plot, thereby monitoring and guiding said ongoing clinical trial on an adjustable and real-time basis.
2. The system of claim 1, wherein said set of subject data comprises unblinded data or one or more accumulative effects derived from said unblinded data.
3. The system of claim 1, wherein said undesirable region comprises a futility region, and said favorable region comprises a successful region.
4. The system of claim 3, wherein said GUI provides a recommendation, wherein said recommendation is:
 - a. "early termination for success" if said accumulative effect falls into said successful region;
 - b. "early termination for futility" if said accumulative effect falls into said futility region;

- c. “continuation without modification” if said accumulative effect falls into said favorable region but not said successful region;
 - d. “continuation with sample size re-estimation” if said accumulative effect falls into said hopeful region; or
 - e. “continuation with caution” if said accumulative effect falls into said undesirable region but not futility region.
5. The system of claim 1, wherein said accumulative effect is one or more statistical scores selected from the group consisting of Score statistics (B value), Wald statistics (Z value), point estimate $\hat{\theta}$, and 95% confidence interval, conditional power (CP), type I error and type II error.
 6. The system of claim 1, wherein said boundary parameters have desirable values that are phase- or time-specific.
 7. The system of claim 1, wherein said system is in operation with a simulation module which conducts simulations in view said set of subject data as accumulated and its trend of said plot, predicts trend and trajectory of said ongoing clinical trial in the future and optionally proposes a clinical trial parameter adjustment by comparing with an initial or existing clinical trial design and assumptions used for said initial or existing clinical design.
 8. The system of claim 7, wherein said simulations are conducted with a trend analysis.
 9. The system of claim 8, wherein said trend analysis is a piecewise linear analysis in which different weights are assigned to each piece showing a linear trend.
 10. The system of claim 1, wherein the favorable region corresponds to a region where the B value is no less than $b_1(t, 1-\beta)$; the hopeful region corresponds to a region where the B value is less than $b_1(t, 1-\beta)$ but no less than $b_2(t, R_{\max})$; and the undesirable region corresponds to a region wherein the B value is less than $b_2(t, R_{\max})$; wherein said $R_{\max}$ is a maximum sample size ratio of said ongoing clinical trial at time t.

11. The system of claim 3, wherein said futility region corresponds to a region wherein the B value is no more than $b_f(t)$, wherein $b_f(t)$ is the threshold value at time t indicating a statistically significant conclusion for futility and said successful region corresponds to a region wherein the B value is no less than C_s , wherein C_s is the threshold value indicating a statistically significant conclusion for success.
12. The system of claim 1, wherein said group of regions in said plot are marked by different colors or patterns.
13. The system of claim 1, wherein when said ongoing clinical trial falls into said the hopeful region for 10 points consecutively, the system provides a signal indicating necessity to adjust one or more clinical trial parameters of said ongoing clinical trials.
14. A graphical user interface-based method for monitoring and guiding an ongoing clinical trial on an adjustable and real-time basis, comprising:
 - a. storing information from an ongoing clinical trial into a clinical trial database, wherein said information comprises a set of subject data that is being continuously updated as said ongoing clinical trial proceeds;
 - b. mapping boundaries, via a boundary determination module, for a group of regions comprising a successful region, a favorable region, a hopeful region, an undesirable region and a futility region, wherein said boundaries are subject to boundary adjustment as said ongoing clinical trial proceeds, wherein each region represents a different level of risk associated with an accumulative effect of said ongoing clinical trial;
 - c. conducting said boundary adjustment on a graphical user interface (GUI), wherein said GUI displays a plot of said accumulative effect of said ongoing clinical trial and boundary parameters corresponding to said group of regions, said GUI allows a user to adjust values of said boundary parameters in view of said plot, thus generating new boundaries on a real-time basis as said ongoing clinical trial proceeds, wherein said accumulative effect of said ongoing clinical trial is continuously projected onto said plot; and
 - d. providing, via said GUI, a recommendation guiding said ongoing clinical trial, wherein said recommendation is:

- 1) “early termination for success” if said accumulative effect falls into said successful region;
- 2) “early termination for futility” if said accumulative effect falls into said futility region;
- 3) “continuation without modification” if said accumulative effect falls into said favorable region but not said successful region;
- 4) “continuation with sample size re-estimation” if said accumulative effect falls into said hopeful region; or
- 5) “continuation with caution” if said accumulative effect falls into said undesirable region but not futility region.

15. A graphical user interface-based method for diagnosing an already completed clinical trial, comprising:

- a. sequentially applying information from an already completed clinical trial into a clinical trial database according to time of patient data completion, wherein said information comprises a set of subject data that is being continuously updated;
- b. mapping boundaries, via a boundary determination module, for a group of regions comprising a successful region, a favorable region, a hopeful region, an undesirable region and a futility region subject to boundary adjustment as said information is being applied, wherein each region represents a different level of risk associated with an accumulative effect of said clinical trial;
- c. conducting said boundary adjustment on a graphical user interface (GUI), wherein said GUI displays a plot of said accumulative effect of said ongoing clinical trial, and boundary parameters corresponding to said group of regions, said GUI allows a user to adjust values of said boundary parameters in view of said plot, thus generating new boundaries assuming said clinical trial was proceeding, wherein said accumulative effect of said clinical trial is continuously projected onto said plot; and
- d. providing, via said GUI, a diagnosis of said clinical trial assuming said clinical trial was proceeding, wherein said diagnosis is:
 - 1) “early termination for success” if said accumulative effect falls into said successful region;
 - 2) “early termination for futility” if said accumulative effect falls into said futility region;
 - 3) “continuation without modification” if said accumulative effect falls into said favorable region but not said successful region;

- 4) “continuation with sample size re-estimation” if said accumulative effect falls into said hopeful region; or
- 5) “continuation with caution” if said accumulative effect falls into said undesirable region but not futility region.