

Redefining big-data clinical trial (BCT)

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An earlier paper initially described the “big-data clinical trial (BCT)”, and found the prospective random controlled trial (RCT) did not win the “relay race” (1). This article discusses the BCT again, in the hope that BCT will win the “relay race” this time.

The one who wins the battle against diabetes mellitus (DM): endocrinologist or data scientists?

In an era of information explosion, stimulating the development of clinical treatment based on big data has become possible. For example, consider the Google contact glass in the Google I/O. This product can collect the real-time blood glucose information of whoever is wearing it and send continuous data to mobile devices, such as a mobile phone, to complete the dynamic collection of glucose. If the subcutaneous insulin pump can be connected to the patient's blood glucose values, which is only one step further, we may be able to obtain nearly perfect glucose values. Therefore, we can predict that in the near future, the victor over diabetes might be the data scientist from Google, but not an endocrinologist.

By analyzing and reconstructing the data produced in the daily life, a brand new world that is built by the data is on the way. The roles that the data scientists played are no longer restricted in data itself, when combined with specific teams, the big data will result in big chances.

The revolution from RCT to BCT: the horses are killed by the steam power

The value of the BCT will become more and more significant in medical research. Before epidemiologists

obtain virus samples, the flu prediction model built by Google and based on search information can be quicker than the Centers for Disease Control and Prevention (CDC) computer on the prediction of flu outbreaks. Therefore, the traditional causal relationship has been broken. The correlational relationship that is the focus of big-data research will take the place of causal relationships as a new key to solve medical problems.

If we compare the two methods in predicting flu, one could easily draw the conclusion that the BCT is both safe and efficient. Costs less, no touching with the biohazard samples etc. (2).

Massive data analysis does not equal BCT. BCT is not only about big data but contains two dimensions: on one hand, focusing on all of the data of a single individual; on the other hand, focusing on a group of individuals to seek a whole sample to represent the real world. The “individual” here does not equate to “patient” because the BCT concerns research on healthy groups in addition to patients.

- Data acquisition: the data collection of BCT shall combine initiative and passive behavior, with the initiative behaviors in the leading position. The so-called initiative behaviors, such as equipping people with devices, will provide information to the database center continuously. Passive behavior reflects data collected by researchers, regularly or irregularly, such as measuring blood pressure and blood tests. The BCT would rely on the technical advances on portable devices, which might be a remarkable point in defining the BCTs.
- Data storage: non-structural, the database will no longer be an X×Y rectangle. The structure of the BCT data is not rectangular but irregular in form.

The current clinical research papers have performed statistic analysis based on rectangular data. For example, the longitude is the data number [1,2,3...], and the latitude is parameters, such as sex and age (with each individual having the same number of parameters). Future BCT data will have an irregular shape because knowledge will change over time. The BCT will continue to adjust the specific parameters to be included, potentially increasing or decreasing the number. And, there could be many types of data recorded in the big-data base, including pictures, videos, and even more, which required new data structure instead of the old one.

- Data analysis: data are analyzed based on the correlations between subjects instead of based on causal relationships (there will be no comparisons in the abstract of the paper; all of the possibilities will be included; the one with the highest correlation will be found; no more problems, as shown in the 4×100 relay race).

In the BCT era, there will be a renovation of the clinical treatment mode for chronic diseases. For example, hypertension patients will be able to obtain real-time blood pressure values anywhere by wearing a device, and the patient will wear “dosing equipment”, subcutaneous or

elsewhere, with which the adjusted dose of drugs according to the fluctuations in blood pressure will be injected to control blood pressure according to the “mandatory program” designed by the doctor based on clinical experience and the patient’s condition.

Although the BCT has many advantages, it is not comprehensive. The greatest threshold to cross is surgery. The treatment mode of internal medicine can be achieved using big-data models. However, surgical technology relies on the brain and the hands of the surgeon. Whether the BCT can provide our surgeons with smart eyes is still open for the imagination.

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