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Can We Automate Clinical Research?

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Clinical research is an expensive, highly manual process, and it is getting more complicated all the time. It employs numerous processes, such as writing protocols, identifying sites, recruiting patients, assessing physical conditions (e.g., patient temperature), and capturing data. One way to reduce costs as well as increase speed and quality is to automate various processes.[1,2]

Process automation involves creating a computer program to replace or streamline a manual process, such as paying invoices or conducting a patient visit. Process automation may employ *artificial intelligence (AI),* typically based on machine learning. Automating a process that includes humans can employ *workflow automation* by which work is prioritized, routed and tracked as it moves within or across organizations. Automation also results in *digitalization* (i.e., elimination of paper).

A fully automated process eliminates manual work, but the benefits of automation can also be achieved with partial automation (e.g., collecting and presenting data to assist with decision making and finding anomalies that need human attention.)

Even fully automated processes need various kinds of human participation:

- Contribute expertise to create the automated process.
- Handle "exceptions" that cannot be automated or are not worth automating.
- Keep an eye on the process to ensure it continues to work correctly.
- Update the process when improvements can be made or the world changes, as it often does.

AI consists of a computer program that analyzes data and supplies the results to assist with human or automated decisions. For example, a wearable device that measures blood glucose levels might control an insulin pump or send a text message to a physician about an out-of-normal-range condition. Numerous very large datasets of patient and healthcare data — prescriptions, insurance claims, electronic medical records, genomics, wearable output, etc. — can be used to train AI computer programs.

Caveats

Implementing an automated system can be costly, time consuming, and risky. To the vexation of software developers, data and processes vary across and within organizations. The lack of standardization is a serious obstacle for automation. Process automation tailored to one set of users can force other users to change their processes in unacceptable ways.

Even assuming the perfect process-automation or AI software program exists, the world will probably change, making the program obsolete. In addition, there may have never been a substantive process-automation software program that did not rapidly generate insatiable feature requests.

Creating an AI program requires large or even vast amounts of data, structured so it can be used to train the AI program. Countless AI failures have occurred because there was not enough data or the data was "dirty" (i.e., faulty or missing). Essentially none of the large databases in healthcare were created for AI training as the primary use.

AI applications can incur other risks: The training database may not represent the study population or include a sub-population. AI applications are notoriously opaque, giving developers and users no insight into the reasons behind the decisions they make. Regulation of AI, especially in healthcare, is immature.

Automation that reduces or removes the human element can be problematic for processes that rely on subjective human judgment or person-to-person relationships, such as ethical review, site selection, site management, informed consent, and patient retention.

Opportunities for Automation

There are numerous opportunities for automation in clinical research, some more useful and practical than others. Solutions already exist for some of these opportunities:

Protocol design. Determine the optimal study population (e.g., patient populations that may react better to the study drug).

Feasibility Analysis. Determine eligibility criteria for a suitable study population.

Translation. Draft translations of consent forms. Detect possible mistranslations.

Ethical review. Prepare and process applications and other documents. Find similar protocols and present any issues, as well as red flags in submitted protocols.

Site selection. Identify sites with the most promising patient populations and those most likely to deliver high-quality data on schedule.

Study selection. Identify studies that best fit the site's objectives and capabilities.

Site management. Automatically collect data about the site(s). Present key performance indicator (KPI) and key risk indicator (KRI) metrics and visualizations to management. Estimate the burden on a site's resources for pricing and staffing purposes.

Clinical trial agreements (CTAs). Compare proposed text to previously agreed text. Suggest text acceptable to both parties. Find missing clauses, drafting errors, and clauses that violate policy.

Study budgets. Compare proposed line items to previously agreed line items. Suggest numbers acceptable to both parties. Find missing line items and numbers that violate policy. Identify potential fair-market-value violations.

Billing compliance. Prepare coverage analyses, detecting gray areas and potential non-compliance.

Training. Record person's training history. Assess current expertise. Suggest training to fill gaps. Tailor training to each person's needs.

Supply chain management. Ship materials based on patient enrollment and visit data. Determine shipment timing and routing. Detect delays and bottlenecks. Forecast shortages.

Patient recruitment. Identify patients likely to qualify for and be interested in studies. Adjust social media recruitment programs (e.g., to improve performance and focus on underrepresented subgroups).

Patient Screening. Rather than use arbitrary eligibility criteria like age, identify patients who are physiologically qualified based on medical record and full-genome analysis and are likely to adhere to protocol requirements and not drop out.

Informed consent. Determine when patient attention is lagging and where follow-up education is needed. Converse with them about the study, answering their questions when

possible and referring others to the principal investigator or study coordinator. Provide feedback on problematic areas in the informed consent information.

Visit scheduling. Schedule study visits based on patient, study coordinator, and resource availability.

Patient identification. Use patient biometrics to ensure identity. Cross-reference against other studies. Validate e-signatures.

Interpretation. Convert spoken language to recipient's language during visits and on the telephone.

Data collection and notes during visits. Convert voice to text and record in the proper place.

Drug dispensing. Automatically record articles dispensed and received by the patient.

Drug accountability. Scan bottles and count pills.

Patient morale**.** Monitor the patient's voice to assess mental state for satisfaction with informed consent and likelihood of enrolling in a study, adhering to the protocol, or dropping out of the study.

Patient data. Collect and analyze patient physical, psychological, adherence and other data with wearables and mobile phone apps.

Payment. Pay patients, sites and solution providers when conditions are satisfied.

Assessments, tests and imaging. Collect and analyze data. Detect problematic incidents and patterns.

Regulatory compliance. Review regulatory documentation for problematic incidents and patterns. Transmit documents between study sponsor and sites.

Quality management. Detect problematic incidents and patterns in source documents. Suggest or take remedial action.

Safety monitoring. Detect problematic incidents and patterns of adverse events. Identify contributing factors such as age, comorbidity or location.

Data management. Monitor study data to detect problematic incidents and patterns.

Biostatistics. Design data structures based on the data and previous protocols. Suggest which analytical methods are most likely to be suitable.

Conclusion

Numerous opportunities exist to apply automation to clinical research, including many solutions that already exist. Not every opportunity is practical with today's technology, but automation is essential to improve cost, speed and quality in clinical research.

References

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