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Therapeutic Drugs Monitoring and the Consequences for Health and Well-Being

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ABSTRACT: The objective of this paper is to present an overview of therapeutic drug monitoring (TDM) and its consequences for health and well-being by harvesting data from several resources including Online and libraries. Information obtained show that the main goals are to avoid harmful or toxic side effects from an excessive dosage as well as therapeutic failures caused by low compliance or prescribing a medication at an incorrect dosage. It also provides details on which drugs require therapeutic drug monitoring and when. Therapeutic monitoring is necessary because there are limited therapeutic window and may cause toxicity or have no therapeutic effect. Targeted Drug Management (TDM) pertains to the effective administration of medication to individual patients by maintaining medicine applications in blood or plasma surrounded by a designated healing window or range. Using pharmaceutics, pharmacokinetics, and pharmacodynamics information, TDM enables the assessment of a drug's safety and efficacy in a variety of clinical settings.

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Therapy drug monitoring (TDM) is the term used to describe irrefutable research laboratory measures of a biological consideration that, when correctly construed by a doctor, will have a direct impact on medicine prescribing practices (Gawade, 2016). According to Kang and Lee (2009), Targeted Drug Management (TDM) pertains to the effective administration of medication to individual patients by maintaining medicine applications in blood or plasma surrounded by a designated healing window or range. Using pharmaceutics, pharmacokinetics, and pharmacodynamics information, TDM enables the assessment of a drug's safety and efficacy in a variety of clinical settings (Tange *et al.,* 2015). Measurement and evaluation of drug concentrations in bodily fluid are integral components of TDM. Drug pharmacokinetic parameters are clinically assessed by TDM. Pharmacokinetics, sample duration, medication history, and the patient's clinical state must all be understood for interpretation. This write-up seeks to explore the crucial role of Therapy Drug Monitoring (TDM) in enhancing medication management, and how it helps maintain optimal drug levels for effective patient care. It also aims to outline the essential elements of TDM, including the evaluation of drug concentrations in bodily fluids, and highlight the importance of considering various factors for accurate interpretation of results. Furthermore, this write-up will examine the benefits of TDM in ensuring the safe

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and effective use of medications in diverse clinical contexts.

Importance of Therapeutic Drug Monitoring in Optimizing Clinical Outcomes: Therapeutic drug monitoring, or TDM, is the process of testing to determine the amount of a certain medication in your blood. This is done to make sure the prescribed amount of the treatment you take is effective and harmless.

Plasmid concentration measurements (PDC): When starting medication therapy, a doctor might discover it helpful to evaluate the PDC in addition adjust the prescription based on the patient's needs. PDC measurements can be useful in a number of situations. Theophylline, carbamazepine, phenytoin, lithium, cyclosporine, and amino glycoside antibiotics are among the medications for which this recommendation is particularly crucial, but it is applicable to all medications (Duhme, 2017).

Monitoring in overdose: The dosage and amount of poisoning consumed, the patient's history, the clinical evaluation, and the interpretation of laboratory results from supplementary tests continue to be crucial to the course of treatment of poisoned patients. For a small number of chemicals, measuring medication concentrations has practical significance. Medicine concentrations are particularly significant for substances like paracetamol, lithium, digoxin, and iron when the patient is otherwise asymptomatic but the dosage suggests serious toxicity (Atkinson and Nordstorm, 2016).

Lessen toxicity: For drugs with a narrow therapeutic index, Physicians recommend monitoring drug concentration levels to minimize side effects, since a small amount on the upper side might have hazardous consequences and a smaller amount can have sub-therapeutic results. Amikacin, phenytoin, theophylline, and digoxin and lithium are examples of medications; aminoglycoside antibiotics include gentamycin and tobramycin. Taking aminoglycosides as prescribed each day will help patients heal better and experience fewer adverse effects, like nephrotoxicity and ototoxicity. Interaction between drugs: drug concentrations in blood are changed, drug metabolism is increased or decreased, and the medication's intended action is ultimately impacted by enzyme induction or inhibition. A growing approach to illness prevention and treatment, precision medicine takes into account a person's unique genetic makeup, lifestyle, and environment.

In this patient population, the pharmacokinetics of these medications in combination might be better understood through measurement of circulating drug levels (Duhme, 2017).

Principles of Therapeutic Drug Monitoring: In real life, TDM is carried out by drawing blood at a predetermined time after the last (or subsequent) dose is given. The medication and/or metabolite applications in the sample are measured and then contrasted with the drug's anticipated pharmacokinetic range or target range (Shenfield, 2015). Within a specific therapeutic window, that is, to customize a dose schedule for each patient (Touw, 2015). Assessment of anti-drug antibodies and drug concentrations, which are linked to endoscopic and clinical results, is part of therapeutic drug monitoring. Therapeutic drug monitoring is both clinically and probably economically beneficial for patients whose anti-tumor necrosis factor treatment response has diminished (Heron and Afif, 2017). TDM involves working with a team usually made up of scientists, doctors, nurses, and pharmacists to make sure precise and clinically significant medication absorptions are achieved. To guarantee that preeminent practices in TDM are realised, excellent communication between team members is required (Ohning, 2014). New indications for medication monitoring include drug-drug interactions, toxicity prevention, efficacy, compliance, and therapy cessation monitoring (Tange *et al.*, 2015).

Drugs Requiring Therapeutic Drug Monitoring: A drug's therapeutic window is the range of concentrations that offers effectiveness without undue harm (Amitava, 2019). Because NTI medicines devise a limited therapeutic window, cautious dosage titration and close by intensive care are typically necessary. Although there are no widely accepted lists of NTI-drugs in the literature, NTI-drugs are generally defined as medications with a slight variation in the range of plasma concentrations that results in both toxicity and efficacy (Amitava, 2019). Amicarbazides, ciclosporin, carbamazepine, digoxin, digitoxin, flecainide, lithium, phenytoin, phenobarbital, rifampicin, theophylline, and warfarin were identified as NTI-drugs. Non-NTI drugs (i.e., all additional medications not mentioned above in particular) and NTI drugs were separated out of the drugs.

Methodologies and Techniques used in Therapeutic Drug Monitoring: The following are the analytical approaches used in TDM.

Spectrophotometry and fluorimetry: Drug samples were examined using spectrophotometric techniques before the development of Gas-Liquid Chromatography (GLC) and High-Performance

Liquid Chromatography (HPLC) (Buchanan, 2018). High specificity, accuracy, and sensitivity are possessed by HPLC and GLS techniques. It is also possible to perform several analyses. A step for extraction is necessary, single serial analysis is slow, columns deteriorate over time, and extensive processing is needed for comprehensive analyses. These are the drawbacks of these approaches. The third method is called Radio Immuno Assay (RIA), which uses radionuclides but is sensitive and reasonably accurate. The method's possible drawback is cross-reactivity with other medications that react similarly (Usman, 2019). The only benefit that enzyme immunoassays have over radioactive isotope extraction (RIA) in that no radioactive tracer is needed, and the bound and unbound fractions don't need to be separated. The fifth assay method is called Fluorescence Polarisation Immunoassay (FPIA), which provides direct assessment without requiring a separation process by combining fluorescence polarisation and competitive protein binding (Usman, 2019). The basis of immunoassays is the binding of an antibody to an antigen. This reversible reaction is influenced by a number of variables, including temperature, pH, the antigen and antibody concentrations, and the antibody's affinity for the antigen. Analytes in biologic matrices can be found and measured utilizing immunoassay techniques by following this link. Immunoassays are exciting for regular analysis in clinical settings, especially for type 2 diabetes. This method has numerous benefits: It is simple to use, enables automation, can be replicated across labs, and is validated. However, there are certain drawbacks to immunoassay that may prevent its widespread use in TDM. The drug concentration interpretations may be incorrect due to significant interassay imprecision, low specificity caused by cross-reactivity between drug and parental metabolites, and wide variations in the lower limit of detection amongst immunoassay analytical techniques. (Sonntag, 2019).

Role of Therapeutic Drug Monitoring in Individualized Therapy: Individualizing medication plans for the best possible patient benefit is the aim of this method. Drug concentrations are measured in a variety of bodily fluids and then interpreted in terms of pertinent clinical factors in traditional dosage-distribution methods (Kang and Lee, 2014). Pharmacologists and clinical pharmacists evaluate these interpretations using pharmacokinetic principles. In the 1960s, the field of TDM introduced a novel aspect to clinical practice with the publication of initial pharmacokinetic studies that linked mathematical theories to patient outcomes (Reed and Blumer, 2016). Therapeutic range creation could reduce this incidence. The development of clinical pharmacokinetic monitoring was aided by developments in analytical technology, high-throughput computerization, drug pharmacokinetic characteristic mapping, and expanded knowledge of drug concentration-response correlations (Kearns *et al*, 2017). To give the best possible therapeutic treatment, maintaining blood medication concentrations within a therapeutic range is the goal of therapeutic drug monitoring (Abudulla, 2023). Drug concentrations, particularly those of serum and plasma, are what we need to monitor in this situation. The phrase "therapeutic range" refers to a range of pharmacological dosages where there is a reasonably high likelihood of the desired clinical response and a relatively low likelihood of unacceptable toxicity (Adam, 2018).

Application of Therapeutic Drug Monitoring: TDM in the Management of Chronic Diseases like Epilepsy, Inflammatory Bowel Diseases, and Organ Transplantation: Therapeutic drug monitoring (TDM) is the procedure that involves determining and applying drug concentrations in serum, plasma, or saliva in a clinical context to alter a patient's dosage and regimen in accordance with their unique pharmacological requirements (Patsalos 2018). As a recurrent disorder that can last for years or a lifetime, epilepsy usually first appears in childhood and many of its sufferers require long-term therapy. The most effective way to direct patient care with antiepileptic medications (AEDs) is when the blood levels have a clear therapeutic meaning and a diagnosis (Patsalos *et al* 2018).

TDM in Optimizing the Use of Biologic Therapies: TDM is the assessment of serum levels of drugs and/or anti-drug antibodies (ADA). Large molecules like biologicals call for more complex analytical techniques (Akobeng at el 2014). TDM may be beneficial depending on the clinician's perspective in a number of different therapeutic scenarios, including treatment resistance, adverse effect comprehension, and dosage modifications. Antibodies linked to biologic treatments (ADAs) are generated when the immune system identifies them. This period has seen a revolution in the treatment of IBD patients thanks to biologics such as anti-tumor necrosis factor (anti-TNF) medicines, as well as the usage of additional classes such as selective adhesion molecule and interleukin 12 and 23 inhibitors. Moreover, since IBD specialists around the world have embraced the "treat to target" strategy in IBD management, the objectives of therapy have also evolved in tandem with advancements in IBD treatment (Peyrin-Biroulet *et al* 2015). One crucial weapon in the toolbox for treating IBD is

therapeutic drug monitoring (TDM), which measures drug concentration and antibody levels to maximize biologic exposure and reduce potential toxicity.

Cost-Effectiveness of TDM in Improving Treatment Outcomes: By decreasing the use of irrational medicines and optimizing medication and dosage selection, including TDM into treatment management reduces health care costs while improving clinical results and safety. (Papamichael, 2019). This notion is supported by the fact that by optimizing dosage, physicians can reduce the likelihood of adverse drug responses, their management costs, and the time spent treating patients (Bejan-Angoulvant *et al* 2017). Cost-effectiveness analysis examines the costs and results of different treatment choices to evaluate the consequences of their application in order to assist physicians, patients, society, or payers in making decisions (Kernick 2013).

TDM in Pediatric Patients and Its Unique Considerations: Early in life, pharmacokinetics rapidly change in children due to physiological changes. Especially between the ages of 6 months and about 6 years, most AEDs that have been studied in the youngest children have low elimination half-lives because of high clearance. Additionally, the distribution's volume varies (Verotti *et al.*, 2019). The clinical effect is that, compared to older children and adolescents, babies and early children frequently require a greater dosage per kilogram of body weight. It is challenging to anticipate the ideal therapeutic dosages because of the significant pharmacokinetic variability during development; TDM may be especially beneficial in these patient groups. It may be necessary to crush, dissolve, or quickly prepare adult formulations as liquid in order to assure consumption and modify the dosage in children. If trustworthy data regarding these modifications are lacking, TDM could potentially support secure and efficient treatment in pediatric settings (Raffaele *et al*., 2022)

Consequences for Health and Well-Being: Impact of TDM on Patient Safety and Treatment Efficacy: Top international professional bodies have designated therapeutic drug monitoring (TDM) as the cornerstone of individualised prescription therapy (Jerome, 2019). The contribution of TDM to enhancing the safety and effectiveness of antibiotic therapies, however, is hotly contested in the critical care setting (Suthakaranand and Adithan, 2021). Particular focus has been placed on intravenous medications, particularly broad-spectrum beta-lactams (penicillins, cephalosporins, and carbapenems), because to their extensive and frequently empirical use, as well as the lack of information regarding the optimal technique to deliver them. A wide range of dosing regimens, significant interindividual variability in the pharmacokinetic properties of these substances, and instability in the patients' clinical status make underdosing a risk for patients, even though toxicity is less of a concern than with glycopeptide or aminoglycoside antimicrobials (Ghiculesco, 2018).

Role of TDM in Preventing Drug Toxicity and Adverse Effects: Therapeutic concentrations in blood, plasma, or other bio-samples are measured by TDM in order to establish the best possible therapeutic dosage for a given patient (Clarke, 2016). According to Ate (2020), chromatographic procedures that can be combined with immunoassays or other detection methods have been among the techniques that have traditionally presented obstacles, restricting its acceptance. The chromatography methods' high sensitivity and specificity, coupled with their simpler protocols, lower costs, and higher throughput flexibility, have resulted in low specificity, while the immunoassay approaches' low specificity have hindered their wider application, despite their inherent value (Carlier *et al*., 2015). Both approaches have limitations. Newer technology advancements, however, will make it possible for TDM to be used in more clinical and scientific settings.

Role of TDM in Preventing Drugs Toxicity and Adverse Effects: Apart from offering a more all-encompassing perspective on how drug concentrations vary over time, continuous TDM can enhance less drug toxicity, improve therapeutic dose optimization and therapy selection, and make it easier to characterize PK dynamics inside and across people. Therapeutic medication monitoring can be used to prevent adverse drug effects as well. Revision of the traditional therapeutic drug monitoring strategy is currently necessary to prevent drug toxicity because of new developments in information technology, innovative analytical methods for drugs not regularly monitored, and updated clinical pharmacological expert opinions in the reporting of laboratory medicine results. Therapeutic drug monitoring can now be used to prevent adverse drug reactions rather than try to figure out what caused a bad medication response that had already happened.

Importance of TDM in Avoiding Drug Resistance and Treatment Failure: Treatment failure is undoubtedly complicated and can be attributed to pharmacokinetic factors, therapy noncompliance, and the emergence of antiviral resistance. In hospital and general medicine settings, laboratory tests are increasingly playing a big role in the decision-making process for doctors. Laboratory investigations are quite important for

advancing diagnosis for doctors and for tracking and overseeing the therapy plan.

Future Implications and Advancements in TDM for Enhancing Health Outcomes: There is potential to improve the effectiveness and accessibility of TDM services. Thanks to technological developments in data analytics, laboratory automation, and remote monitoring. Patient outcomes can be enhanced and TDM's reach can be increased through the use of digital platforms and telemedicine technologies. To bring pharmaceutics to the appropriate concentrations, therapeutic drug monitoring (TDM) of plasma tasters is frequently employed. Antiepileptic medications, anticoagulants, and immune modulators are examples of medications with a narrow therapeutic window that are typically used when significant inter- and intra-individual variability in concentrations are anticipated. The market for TDM services is expanding as a result of rising rates of chronic illnesses and rising demand for individualised drug schedules. Drug monitoring services that are precise and prompt are becoming more and more necessary as the quantity of patients who need lasting medicine keeps rising. The uptake of TDM services is being aided by developments in diagnostic and analytical technologies. Enhancing drug monitoring's precision and effectiveness is the creation of new analytical instruments and enhanced testing procedures.

Case Studies and Research Findings: Studies Showcasing the Benefits of TDM in Different Medical Conditions: These patients have serious infections and are at risk for infection, treatment optimisation (TMD) is typically implemented in the critical care unit and because of their condition, critically ill patients may have notable alterations in their renal clearance and liver function. Fluid augmentation therapy, systemic inflammation, dialysis, and/or extracorporeal membrane oxygenation all exacerbate the resulting poorly predicted pharmacokinetic profiles (Kernick 2013). Variations in drug exposure can therefore be caused by changes in protein binding, volume of distribution, and clearance (Kernick 2013). For critically ill patients, having intravenous catheters makes sampling easier, which is a relative benefit. Variations in drug exposure can therefore be caused by changes in protein binding, volume of distribution, and clearance. One benefit that is somewhat advantageous is that intravenous catheters make sampling easier for people who are extremely sick. TDM is carried out for each patient when it comes to several anti-infectives, including gentamicin and vancomycin, because its advantages in terms of toxicity and efficacy have been demonstrated (Bejan-Angoulvant *et al* 2017). When a patient exhibits a sluggish therapeutic response or there is a suspicion of toxicity or resistance developing, TDM may be recommended for medications that are assessed less frequently, such as voriconazole. To evaluate toxicity, maximise medication efficacy, and track adherence to treatment plans, therapeutic drug monitoring (TDM) can be employed.

Real-World Examples of How TDM Has Influenced Patient Care and Outcomes: Study by Carsten Müller *et al*, (2017) reported cases of how TDM has influenced patient care and outcomes.

Case 1: Intoxication with clozapine due to inflammation-induced enzyme inhibition is described in the first instance of a female patient, 64, who has a history of paranoid hallucinating schizophrenia. Intoxication was characterized by drowsiness, significant limitations, especially in the areas of focus and cognitive function (psychomotor retardation), hyperglycemia, and momentary swelling. The patient showed no signs of recovery even with a high serum concentration of clozapine at first (Cmax = 1367 µg/l).A 64-year-old female patient's first case of paranoid hallucinating schizophrenia is described, wherein clozapine intoxication results from enzyme inhibition brought on by discomfort. One sign of intoxication was drowsiness; significant limitations were especially prevalent. Hyperglycemia and temporary indications of inflammation, as well as cognitive function (psychomotor delay). The patient fully recovered with no lingering symptoms, even with an initial high clozapine serum concentration (Cmax = 1367 µg/l).

Case 2: In the second instance, we describe a male patient, 35 years old, weighing 80 kg, who experienced an immediate decline in breathing, potentially due to clozapine intoxication (Cmax = 1175 µg/l), necessitating mechanical ventilation and intubation. The following were the signs and symptoms associated with the disease: thrombozytopenia, hyperglycemia, tachycardia, development of bilateral pulmonary embolism, and temporary hypothyreoidism. The patient passed away from multiple organ failure despite the use of extracorporeal membrane oxygenation (ECMO) to increase aggressive medical interventions.

Challenges and Limitations in the Current Practice of TDM: A major barrier to industry expansion is the high expense of TDM services, which includes lab testing and specialised equipment. Particularly in environments with limited resources, adoption may be hindered by the cost of putting TDM programmes into place and keeping up the required infrastructure. The expansion of the TDM market is hampered by the absence of standardised norms and a regulatory

framework. One major obstacle is the lack of knowledge among patients and medical professionals regarding the advantages of TDM and its function in improving treatment results. Promoting the benefits of TDM and dispelling myths requires education and training initiatives. Other challenges includes; the uncertainty about its availability in practice, not enough knowledge about TDM, its interpretation and application of the result, there is a delay between serum sampling and TDM results, TDM is laborious and/or time-consuming.

Ethical and Regulatory Considerations

Ethical Implication of TDM in Patient Care: The ideal amounts for patients receiving Therapeutic drug monitoring (TDM) is used to identify some types of drugs that are difficult to dose. When starting a new medication, a patient could require testing. This aids in the determination of the optimal dosage for you by your healthcare professional. A patient can have repeated testing once that dosage is established to make sure the medication is still beneficial without becoming hazardous. If a patient is experiencing symptoms of a major side effect, he may also require testing. The side effects that come with different drugs vary. Tests for liver and kidney function, as well as the adverse effects of some medications, such as urea and electrolytes, are conducted on a regular basis using creatinine. With monitoring, it is possible to identify declines in the body's capacity to effectively process and remove medications.

Regulatory Guidelines and Best Practices in TDM Implementation: According to Amitava (2019), therapeutic medication monitoring is only necessary for medications having a narrow therapeutic index. As such, only a very small proportion of pharmaceuticals (about 50–60 medications) require regular monitoring. The definition of therapeutic drug monitoring, as agreed upon by the International Association of Therapeutic Drug Monitoring and Clinical Toxicology, is the measurement made in the laboratory of a parameter that, with appropriate interpretation, will directly influence prescribing procedures. Although this is more frequently observed in the biological matrix of a prescription xenobiotic, an endogenous chemical that is given as a replacement treatment for a patient who is physiologically or pathologically low in it can also be assessed. The traditional approach to therapeutic drug monitoring has been to measure the drug's concentration in a biological matrix, usually serum or plasma, and then analyze the results in light of relevant clinical variables. The best matrix for therapeutic drug monitoring of immune suppressants is whole blood, with the exception of mycophenolic acid. To ensure the therapeutic medication monitoring program is successful, doctors, lab staff, and chemists must effectively communicate with one another (Peyrin-Biroulet *et al.,* 2015). Thus, precise determination of the drug level in the relevant biological matrix is essential for the interpretation of test results and any necessary dose adjustment that follows.

Ensuring Patient Confidentiality and Data and Protection in TDM: The security, privacy, and protection of patient medical data are the responsibility of every individual on the healthcare team as well as every company. This is particularly valid in the modern era of quickly developing information technology. Medical personnel would often simply omit the patients' identities when collecting patient data for research. This method of doing things has been abandoned.

Future Directions and Conclusion

Emerging TDM Technologies: Identifying the subjects who would benefit from TDM, the medications that are appropriate for TDM, and how to apply TDM in these situations remain challenging due to individual differences in comorbidity, genetic, epigenetic, behavioral, and environmental exposure profiles (Kang and Lee, 2009). Utilising techniques like wearable and biosensor technologies, medical digital twins, and computer models of actual patients that make use of personal characteristics to predict a patient's potential reaction to an injury, infection, or treatment (Laubenbacher *et al*., 2022). These, in particular, have demonstrated promise for tailoring pain medication management (Bahrami, 2023), and which may be able to overcome these issues, lessen the workload associated with putting TDM tactics into practice, as well as make continuous drug monitoring possible. Two new technologies that are enhancing TDM are wearables and biosensors, which enable the translation of specific assessments on individuals into quantifiable drug-induced signals (Ates *et al*., 2020). A recognition element (antibodies, enzymes such cytochrome P450 (i.e., enzyme-linked assays, ELA), membranes, polymers, or aptamers) typically binds non-covalently to an analyte to cause drug-induced signal detection from, for example, plasma samples (Ates *et al*., 2020). For this operation, optical and electrochemical approaches are most frequently utilized. The fields of clinical laboratory testing, illness diagnosis, and treatment planning stand to benefit greatly from artificial intelligence (AI). By using enormous datasets and trend recognition, artificial intelligence (AI) technology can perform better than humans in a variety of healthcare disciplines. With AI, human error is minimized and costs, time, and accuracy are decreased. It has the

capacity to change population health management, optimize medication dosages, enhance patient education, influence patient-physician trust, establish guidelines, and provide virtual health assistants. It can support mental health therapy as well.

Conclusion: The core insights from the article on Therapy Drug Monitoring (TDM) underscore its vital importance in refining medication regimens and enhancing patient outcomes. By maintaining optimal drug levels, TDM optimizes therapeutic efficacy while minimizing adverse effects. To accurately interpret TDM results, healthcare professionals must consider a range of factors, including pharmacokinetic profiles, sampling timelines, and individual patient characteristics. By leveraging TDM, clinicians can deliver personalized care, streamline treatment plans, and significantly improve overall healthcare quality, thereby reducing the risk of adverse reactions and promoting better patient health. Conclusively, the integration of Therapeutic Drug Monitoring (TDM) is vital for optimizing medication therapy and ensuring patient safety. By providing actionable insights into drug concentrations, TDM empowers clinicians to refine treatment strategies, minimize adverse events, and optimize therapeutic outcomes. Although TDM faces challenges, emerging technological breakthroughs offer unprecedented opportunities for enhancement. To fully leverage TDM's benefits, the healthcare community must emphasize education, standardization, and regulatory guidance. By doing so, we can unlock TDM's potential to transform patient care, reduce healthcare costs, and drive innovation in personalized medicine.

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