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Drug exposure during clinical drug development

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The development of new drugs is currently facing a challenging situation where for most therapeutic areas under investigation the therapeutic index is narrow. In this setting, it becomes essential to identify the optimal dose and dosing regimen that best balance safety and efficacy. This situation points to the need for adherence-informed clinical trials in which exposure to the test drugs is precisely measured to assess dose-dependent effectiveness. In a limited number of circumstances, the investigated drugs show an exceptionally high molecular potency or through a slow release delivery system they can be administered infrequently so that the responsibility for drug administration can be economically transferred to properly trained professionals. Those situations are, however, exceptional, so in most therapeutic situations the patients bear the responsibility for maintaining appropriate dosing in ambulatory care. Research on patient adherence shows that many patients cannot maintain dosing at therapeutically effective intervals. When interdose intervals are too long, drug concentrations in plasma decline; drug actions decline and eventually cease. Short interdose intervals result in concentrations of drug that exceed therapeutic limits and increase the risk of toxicity. Non-intrusive, reliable, and continuous assessment of patient adherence can be achieved by automatic compilation of drug dosing history data using electronic detection of entry into conventionally designed drug packages ("smart packages"). The resulting dosing history data allow one to identify particular dosing errors than can jeopardize treatment outcomes, and can, in turn, be used to focus intervention to achieve full implementation of, and long-term persistence with, the dosing regimen.

Biography

Bernard Vrijens has developed ways of extracting clinical explanatory power from drug dosing histories, as patients variably comply with prescribed regimens in a series of scientific papers. He is building the largest repository of data, publications, and technical documents about electronically compiled dosing histories, in order to identify the most common dosing errors, particular dosing errors that can jeopardize efficacy, and optimal measurement-guided medication management to enhance adherence and maintain long-term persistence. He is the co-author of over 60 peer-reviewed scientific papers, and a founding member and managing director of the European Society for Patient Adherence, Compliance, and Persistence.

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