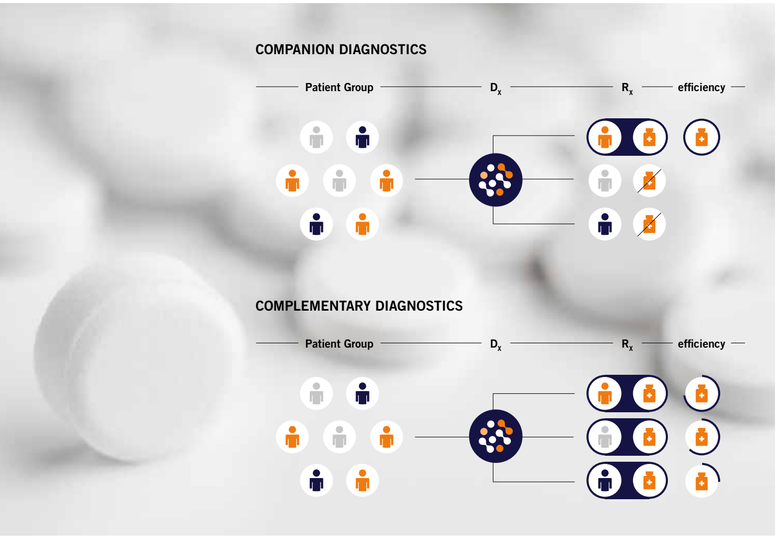
Companion versus Complementary Diagnostics

A Companion Diagnostic assay is a diagnostic test or device (Dx) that provides information that is required for the safe and effective use of a therapeutic drug. A Complementary Diagnostic assay is a diagnostic test or device that identifies patients that respond particularly well to a drug and aid risk and benefit assessment for individual patients, but that is not a requisite for patients to take the drug.



D_x diagnostic test
R_x drug prescription

Companion & Complementary Diagnostics by Eurofins

- >400,000 m² of state-of-the-art laboratories equipped with the latest analytical technology
- Service provider to Top 10 largest global pharmaceutical companies
- From Discovery to Commercialization
- Broad Specialty Diagnostics offering covering all techniques and medical specialties
- Newest Clinical Genetics assays available

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More efficient and safer drugs

Clinical Diagnostics have been supporting the pharmaceutical industry for many years with specialty diagnostics tests. These tests allow the identification of patients that could benefit from a particular treatment. The collaboration between the two industries starts in most cases during late drug development phases, i.e. clinical development, and it is only recently that the benefit of an earlier collaboration has been demonstrated.

Working together from the drug discovery phase to develop a Companion or a Complementary Diagnostics test translates in:

Increased drug efficiency through targeting only those patients that are most likely to benefit from the treatment.

Better drug safety profiles via identification of patients that are at risk of severe adverse side effects allowing dose adjustment or drug discontinuation when necessary.

Personalized treatment thanks to therapeutic drug monitoring which permits the modification of drug administration and/or dose when required.

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Shorter time to market

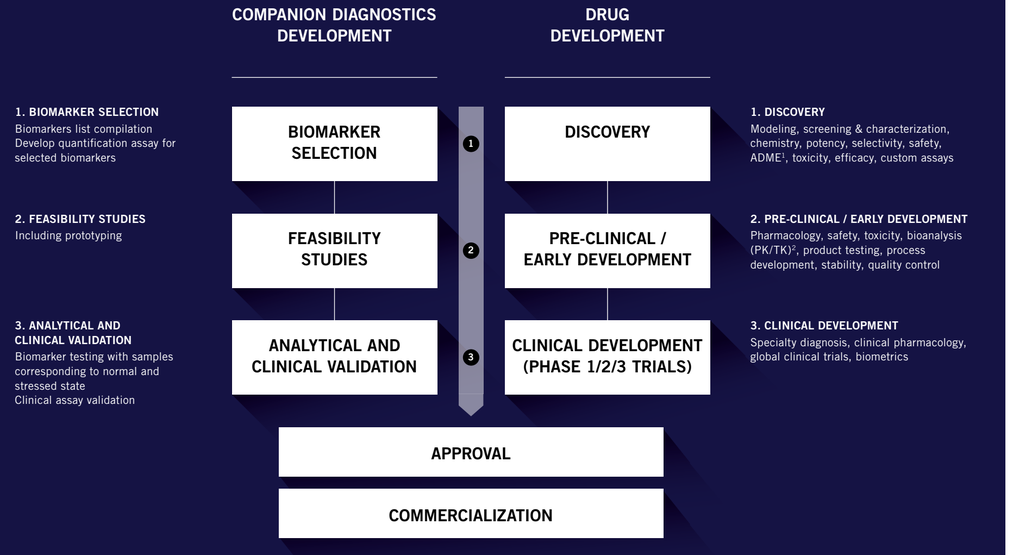
Apart from improving patient outcomes, companion diagnostics enhance the drug development cycle by:

Reducing R&D costs
Selection of the right target patients in clinical trials reduces the cost of the trial (i.e. less patients need to be included in the trial to prove efficacy) and allows faster development (i.e. less patients in the trial implies shorter trial duration too). Companion diagnostics guided trials can significantly reduce the cost of drug development for the pharmaceutical industry.

Increasing drug approval rates
Clinical diagnostic tests allow the classification of patients depending on their genetic and metabolic profiles, thus aiding the adjustment of drug dosage in a personalised manner. Consequently, this reduces undesirable side effects and toxicity. This new approach translates into safer drug profiles facilitating the drug approval process and reducing time to market.

Companion and Complementary Diagnostics development at Eurofins works closely with the pharmaceutical industry to shorten time to market for new important drugs. Being active in all medical specialties, we have experience working with new oncology drugs and innovative therapies for rare diseases among many others.

Eurofins Clinical Diagnostics from discovery to commercialization



APPROVAL AND COMMERCIALIZATION
A new drug will need to get market approval before being commercialized. A new companion or complimentary diagnostic test will need to be approved by the FDA in US and in the case of in-vitro diagnostic devices, certified CE-mark in EU before reaching the market

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[1] ADME: absorption, distribution, metabolism, and excretion
[2] PK/TK: pharmacokinetics / toxicokinetics