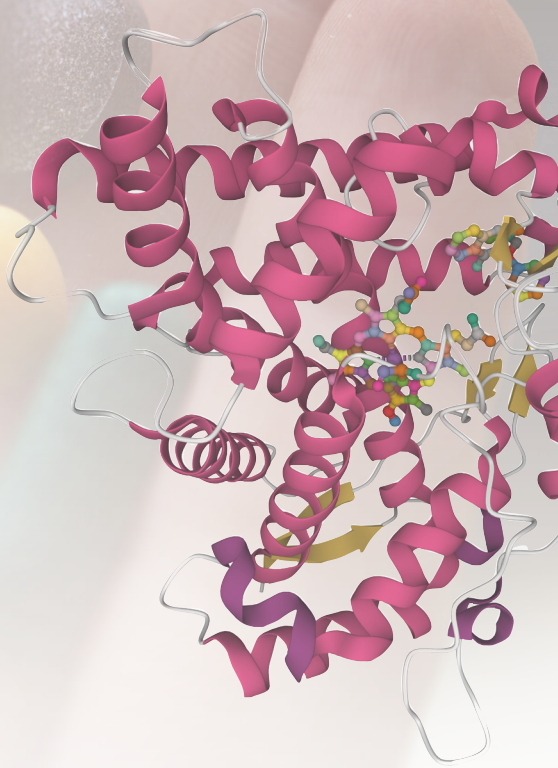
DRUG DEVELOPMENT SOLUTIONS
Part of Alliance Pharma, Inc.

In Vivo DDI Studies

Drug-drug interactions (DDI) pose a significant safety risk in the development of new medicines.

With an increasingly aging global population and a corresponding increase in polypharmacy, incidences of harmful and potentially fatal side effects of DDIs are expected to increase.

This highlights the importance of assessing potential DDIs during drug development and ensuring they are sufficiently characterised prior to market approval of medicines.

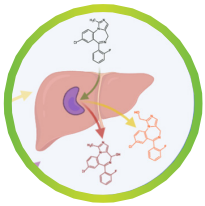


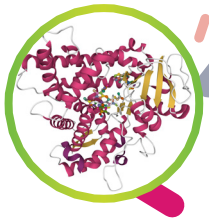
At our Cambridge (Fordham) facility our LC-MS Bioanalysis department has considerable experience supporting *in vivo* DDI studies performed during the clinical phase of drug development.

Clinical DDI study areas we typically support include:

- Quantitation of investigational drug and single probe/inhibitor drug
- PK parameter analysis
- Partial validation to assess assay performance in presence of DDI probes/inhibitor drugs
- Larger, complex studies assessing investigational drugs and multiple DDI probes/inhibitors across multiple cohorts

We have built a portfolio of in-house quantitative assays, with an emphasis on the probe drugs and inducers/inhibitors recommended in guidance issued by the EMA and FDA.



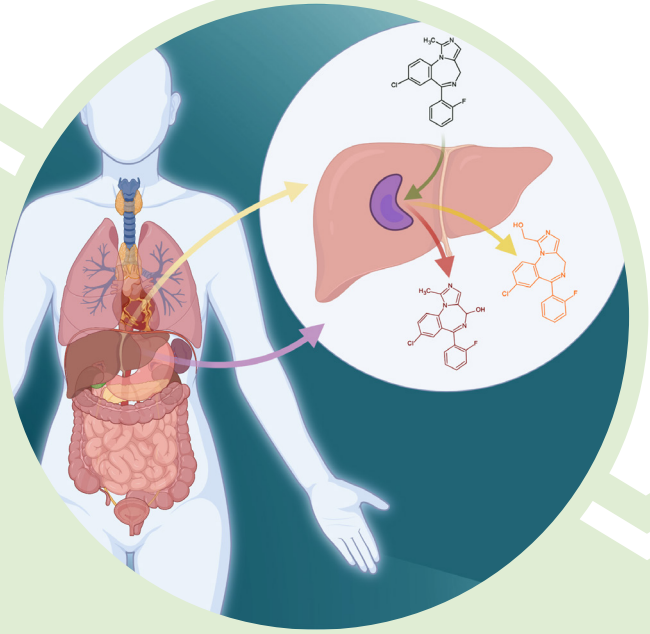


Based on EMA and FDA guidelines, we have targeted the following clinical index probes, inhibitors and inducers to set up in-house LC-MS/MS assays:

Enzyme	Analyte	Category
CYP1A2	Tizanidine	Probe drug
	Enoxacin	Strong inhibitor
	Fluvoxamine	Strong inhibitor
CYP2B6	Efavirenz	Probe drug
	Ticlopidine	Strong inhibitor
CYP2C19	Omeprazole	Probe drug
	Omeprazole	Moderate inhibitor
	Fluvoxamine	Strong inhibitor
CYP2C8	Repaglinide*	Probe drug
	Gemfibrozil	Strong inhibitor
CYP2C9	Tolbutamide	Probe drug
	S-warfarin	Probe drug
	Fluconazole	Moderate inhibitor
CYP2D6	Desipramine*	Probe drug
	Paroxetine	Strong inhibitor
CYP3A	Midazolam*	Probe drug
	Itraconazole*	Strong inhibitor
	Ritonavir	Strong inhibitor
CYP1A2, CYP2B6, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A	Rifampicin	Strong/moderate inducer

*Major active metabolites included

We also have 20+ additional methods in place for concomitant medications and transporter probes.
Contact us for the full list of non-proprietary methods.



Let's discuss your project:
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