

HCV Drug HCV Drugs NDA submissions

Recommendations for for drug - drug
interaction studies

DDI studies: discussion points

- Help field (big bang)
- Neglected areas/overlooked
- Timing of studies in relationship to development

Discussion

- Co-prescribed oral antiviral DAA's:
 - regimen development
 - Drug concentrations
 - Phosphorylation
- Anti-virals with coexisting drugs
- Special populations
 - HIV coinfecting
 - Liver transplant recipients
 - Hepatic impairment
 - Renal impairment
 - Methadone substitution
 - Antidepressant medication
 - Anti-psychotic medication
 - Alcohol use/abuse

Discussion

- Host differences in PK
 - Ethnic differences
 - Gender differences
- Advisory
 - Technical:
 - kind of PK studies
 - Study design
 - Timing
 - Publication of data
 - Labelling
 - Accessibility of information