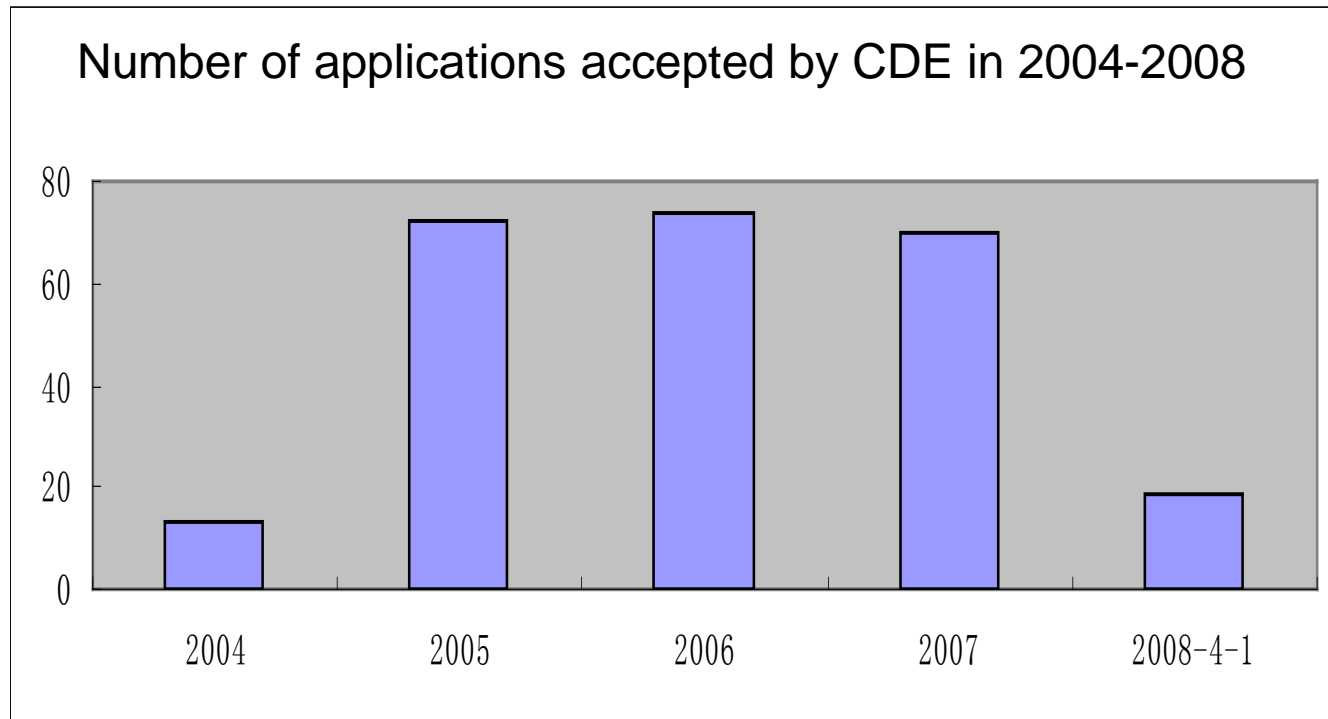


Multinational Clinical Trials in China

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Applications accepted by CDE(2004-2008)



Multinational Clinical Trails in PUFH

Year	Number
2001	4
2002	1
2003	1
2004	6
2005	7
2006	10
2007	7
2008	10
2009	13
201004	4

Categories of Multinational Clinical Trails in PUFH

<i>Pharmacology Division</i>	<i>Number</i>	<i>Pharmacology Division</i>	<i>Number</i>
anti-neoplastic drugs	9	anti-viral agents	2
blood system agents	9	nervous system agents	2
phase I	8	contraceptives	1
immuno-modulators	7	anti-osteoporosis agents	1
anti-infective agents	6	anti-obesity drugs	1
anti-diabetic drugs	6	anti-epileptics	1
cardiovascular system agents	6	anesthetics	1
respiratory system agents	3		

Current Issues of Multinational Clinical Trial

- ✓ Pharmacokinetics
- ✓ Number of Subjects
- ✓ Ethics

Pharmacokinetics Issues

- ✓ Cannot meet the claim of laws and regulations
- ✓ Lack in consider of genetic factors
- ✓ Pharmacokinetics in special populations

Ethic Issues

- Cultural differences: language, diet, lifestyle habits, *et.al*
- Joint IRB



Thanks for attention!