

Safety in Phase I

After the London tragedy....

...more & more attention on safety in Phase I, in

The French Register

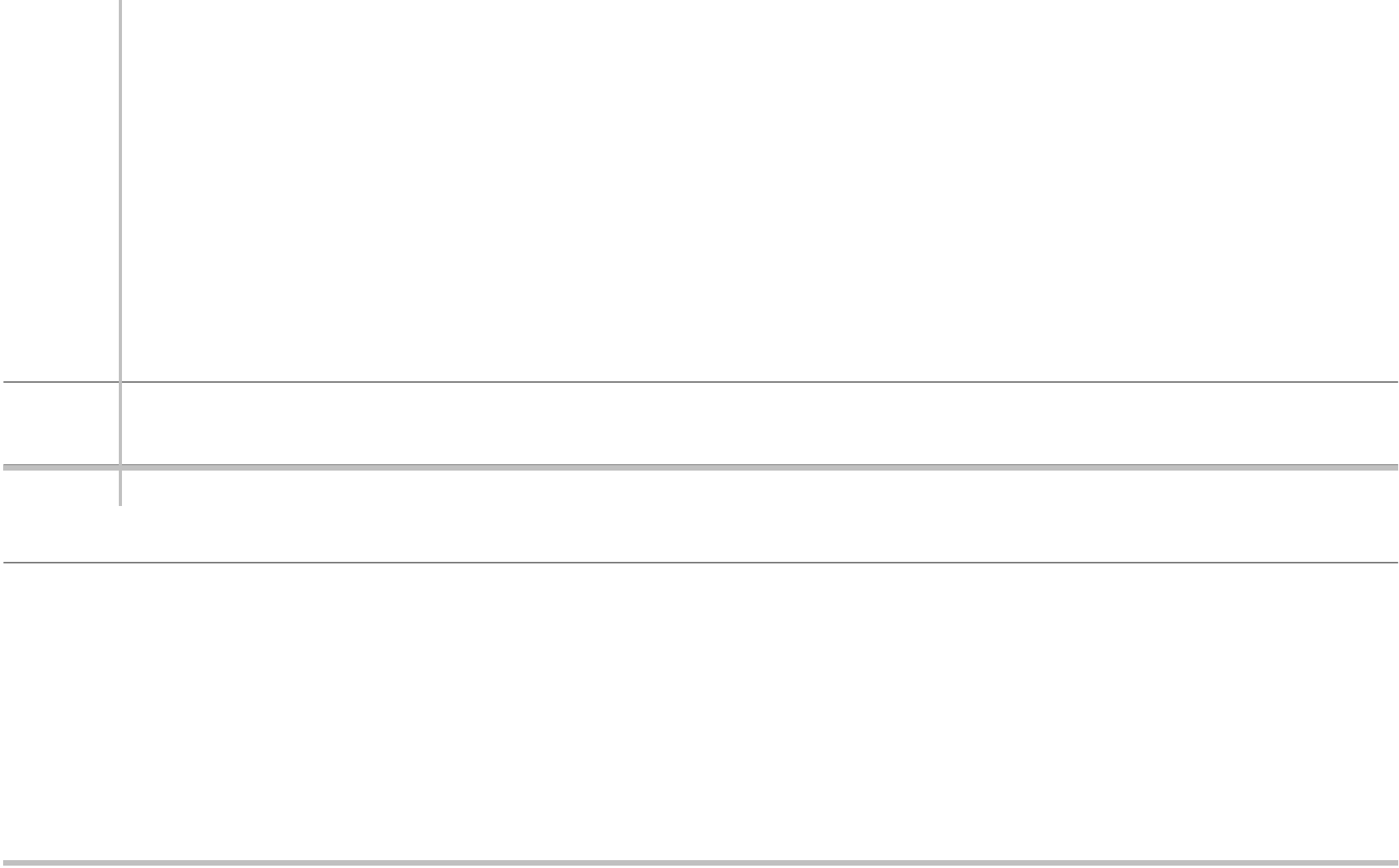
- Sponsor: Club Phase I
- Creation: 2003 à data available on 2004/5[®] & 6
- Mode: Survey sent to CROs
- Scope: Phase I studies
Healthy subjects
SAEs (GCP definition)

© 2004/5 Brit J Clin Pharm, 2006; 62: 502-3

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The Club Phase I French Register Notes

1. “SAEs”
 - Easy to identify



SAEs	ALL
2004	25
2005	35
2006	44
TOTAL	104

SAEs RELATED UNRELAT

SAEs

2004

RELATED

10

Incidence

2 perre

SUBJECTS	RELATED SAEs	RELATED & WORRYING	INCIDENCE PER 1000
5458	10	0	0,0
9928	20	3	0,3
5927	10	5	0,8
21313	40	8	

DEATHS

Number = 4 Incidence = 0,2 per thousand

1. Cancer (lung): elderly woman
2. Motorbike accident: 1 young man
3. Suicide: elderly
4. Suicide: middle-aged man

None being related to the drug

SAEs: most common types

- Intercurrent diseases :

35 (related 0)

Kc (4), Infection (5), Traumatism(15), Surgery (11)

- Liver:

28 (related **25 (90%)**)

including **3 Acute Hepatitis**

Incidence/age

621 *15* *24/1000* 1 1
x 6 !!!

SAEs French Register: Comparison to other registers

1. Japan (93-2004) – 95780 subjects
8000/year

Ⓜ Clin Pharm & Therap 2006; 79:P71

2. UK (AICRC 92-2001) – 92510
9000/year
3. France # 7000/year

Deaths in Phase I and experimental research

N°	Year	Country
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General conclusions

1. Phase I is safe
2. Major risks rarely related to tested drug use:
 - Only 0,4 %/0

General conclusatis

Recommendations

Common: Strict adherence to safe rules
(screening