GCP ICH: A Sponsor's Perspective

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Agenda Topics

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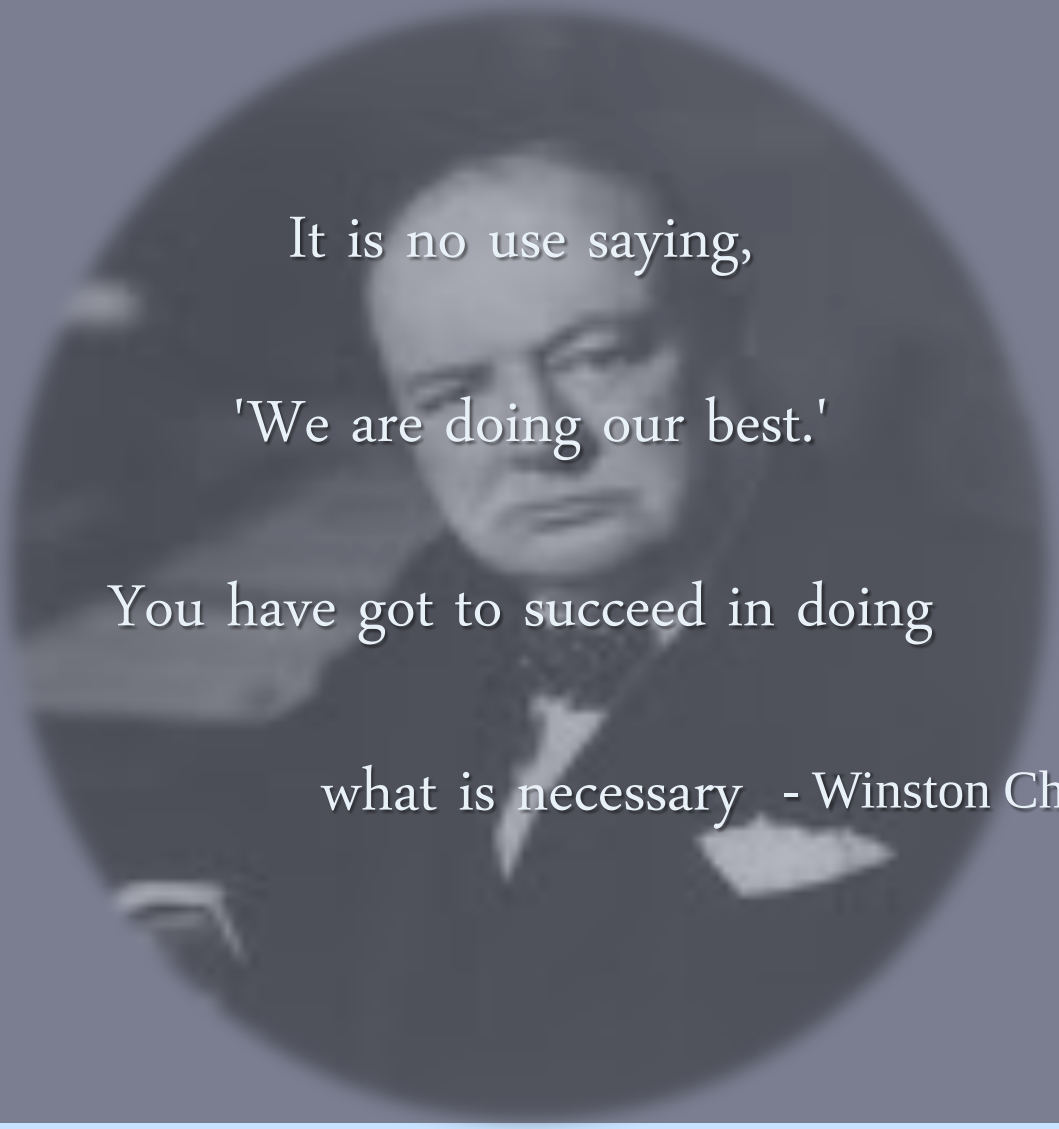
- Sponsor's Role and Responsibilities
- Current Environment
- Impact of Globalization
- Quality In Clinical Trials



It is no use saying,

'We are doing our best.'

You have got to succeed in doing

what is necessary - Winston Churchill

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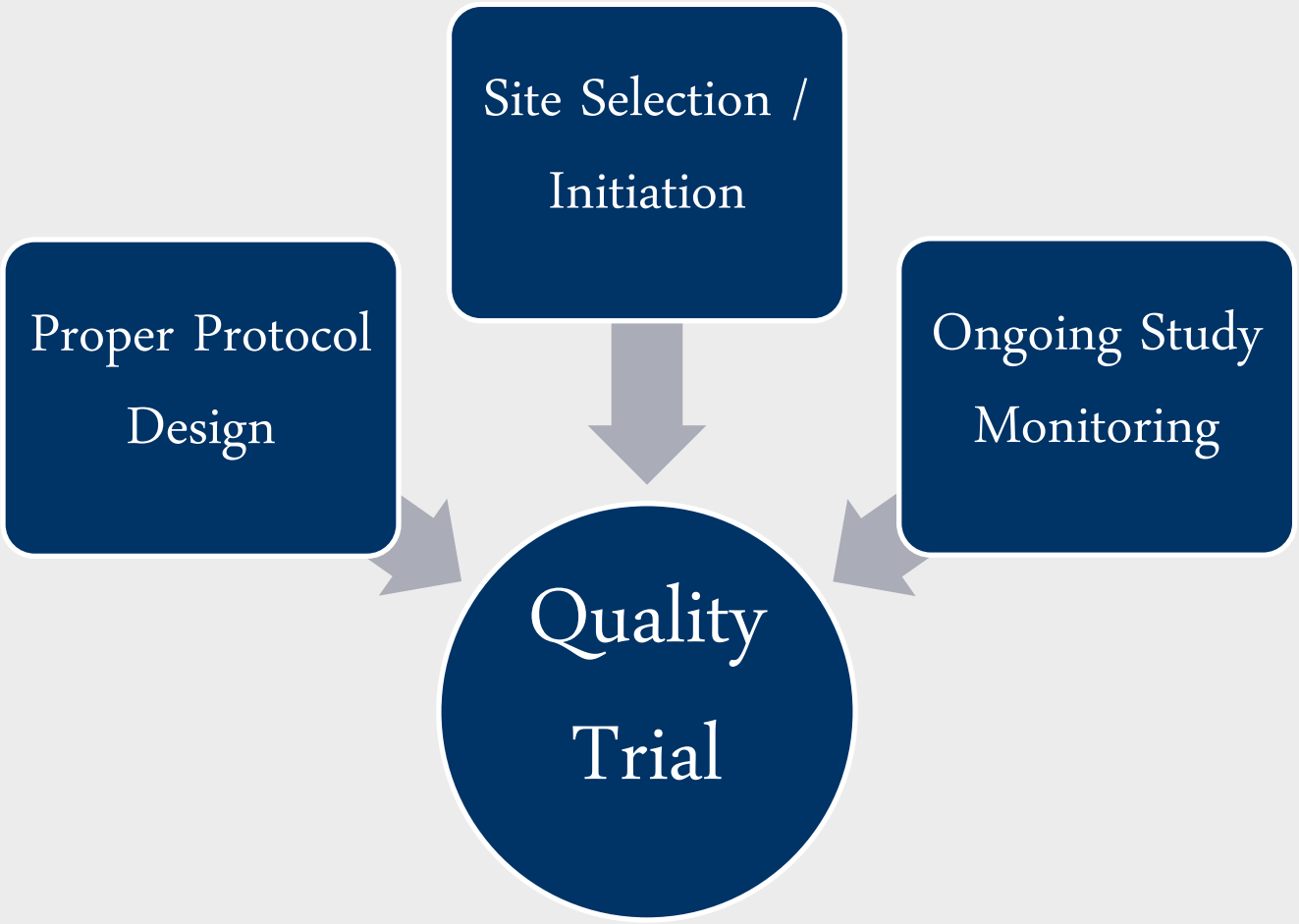

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There is an increased complexity to trial design and conduct.

Complexity of Clinical Trials Has Increased

During the last decade clinical trial designs and procedures have become much more complex.

Source: Tufts Center for the Study of Drug Development, "Growing Protocol Design Complexity Stresses Investigators, Volunteers," *Tufts CSDD Impact Report* 10, no. 1 (2008).

Changes in Clinical Trials: Resources, Length and Participation

	1999	2005	Percentage change
Procedures per Trial Protocol (Median) (e.g. bloodwork, routine exams, x-rays, etc.)	96	158	65%
Clinical Trial Staff Work Burden (Measured in Work-effort Units)	21	35	67%
Length of Clinical Trial (Days)	460	780	70%
Clinical Trial-Participant Enrollment Rate (% of volunteers meeting trial criteria)	75%	59%	-21%
Clinical Trial-Participant Retention Rate (% of participants completing trial)	69%	48%	-30%

Source: Tufts Center for the Study of Drug Development[12]

Source: http://www.phrma.org

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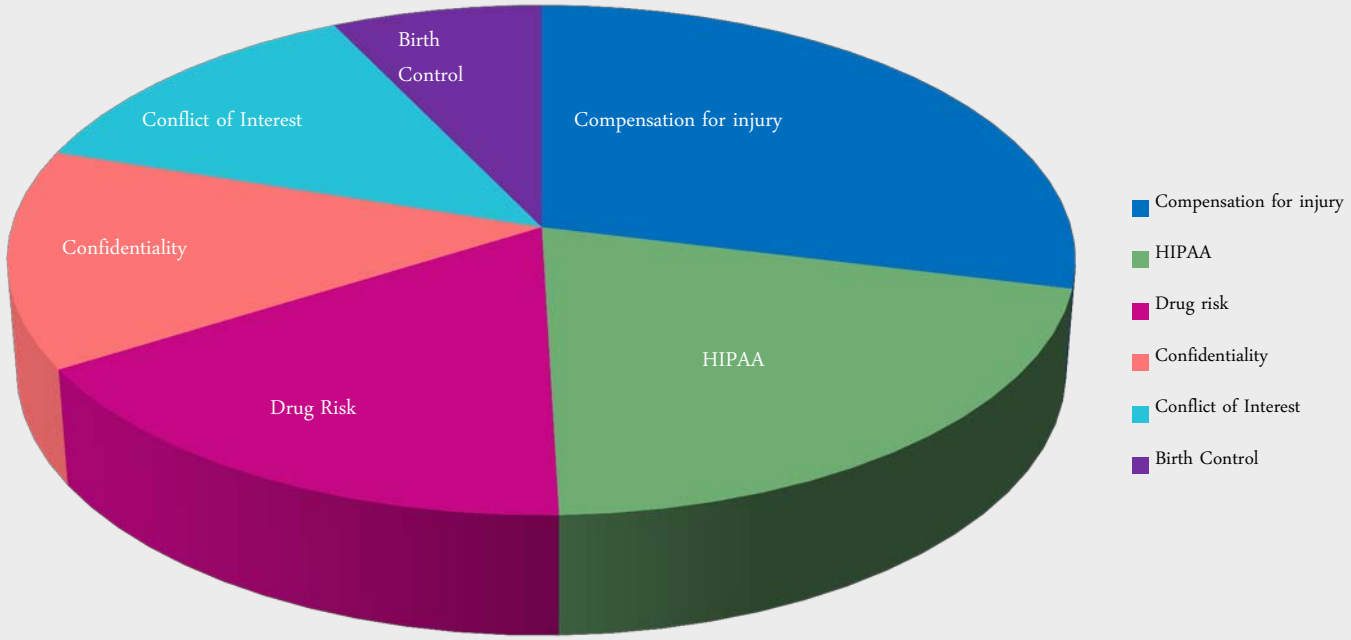
Most Commonly Negotiated Sections of the ICF/HIPAA Changes



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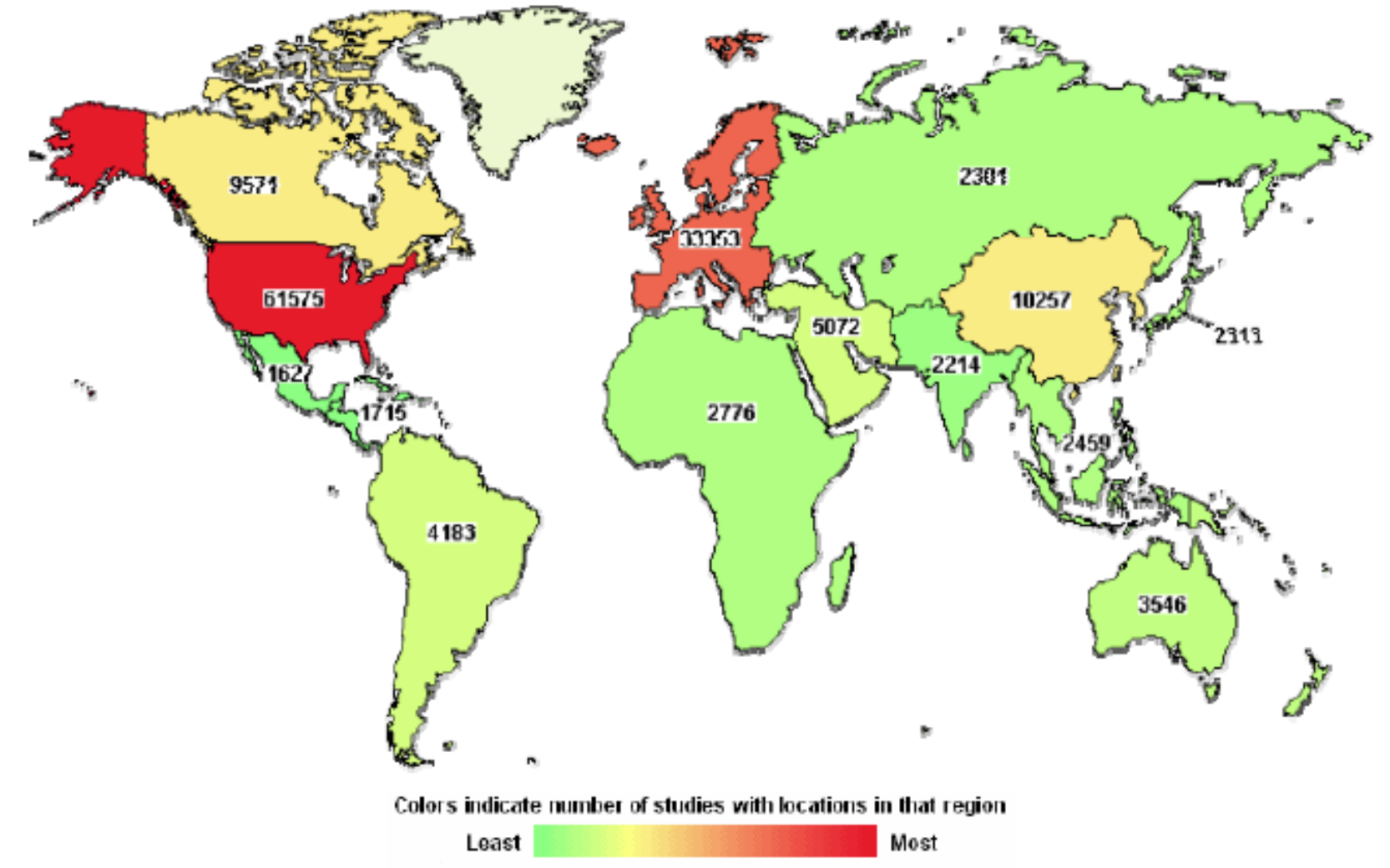

 # Studies Worldwide: 126,295

Source: www.clinicaltrials.gov (search date: 22 May 2012

? Quality in Clinical Trials

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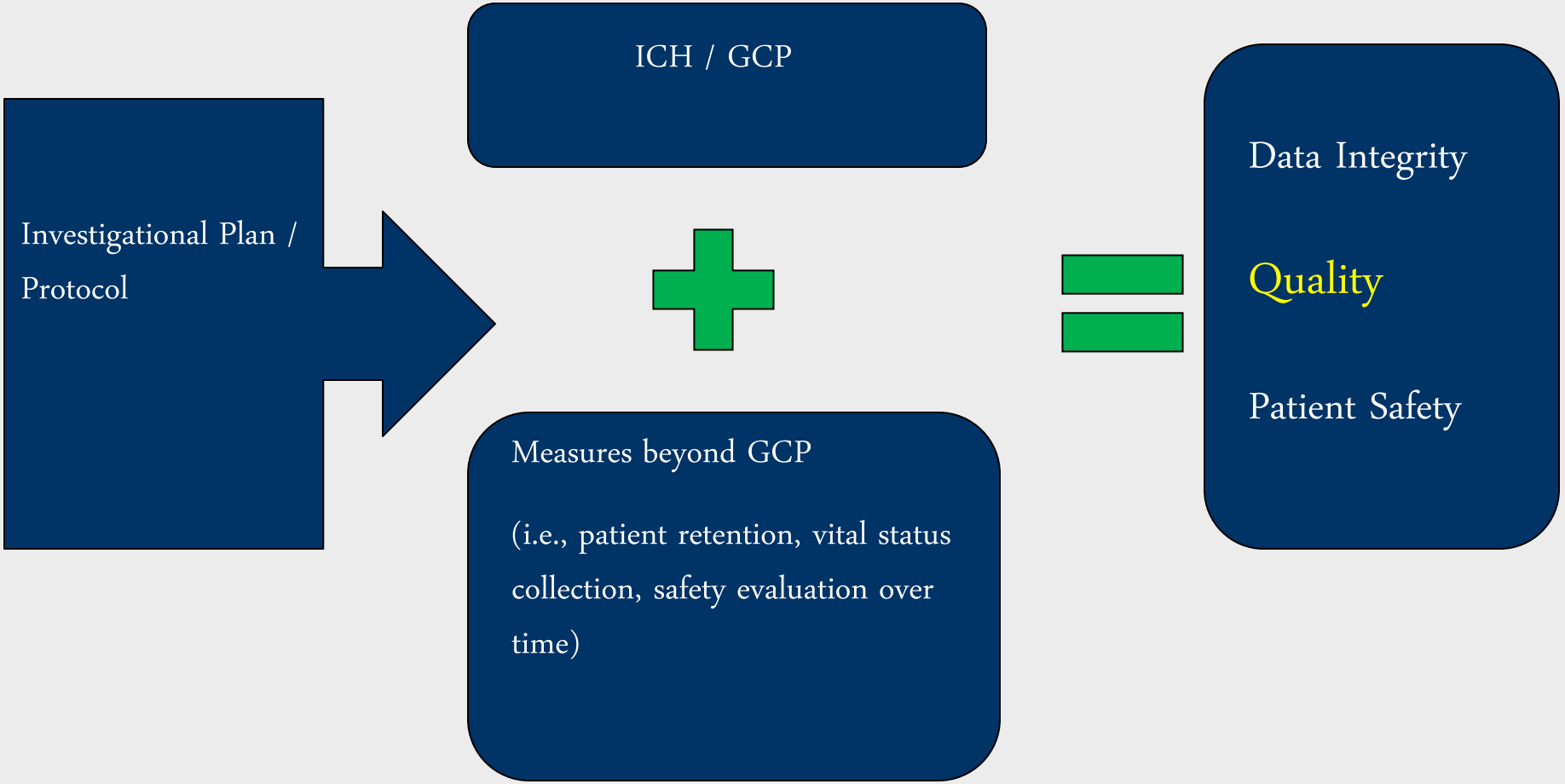

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Thank You