

Welcome to Sitges

PCMG annual conference 2019

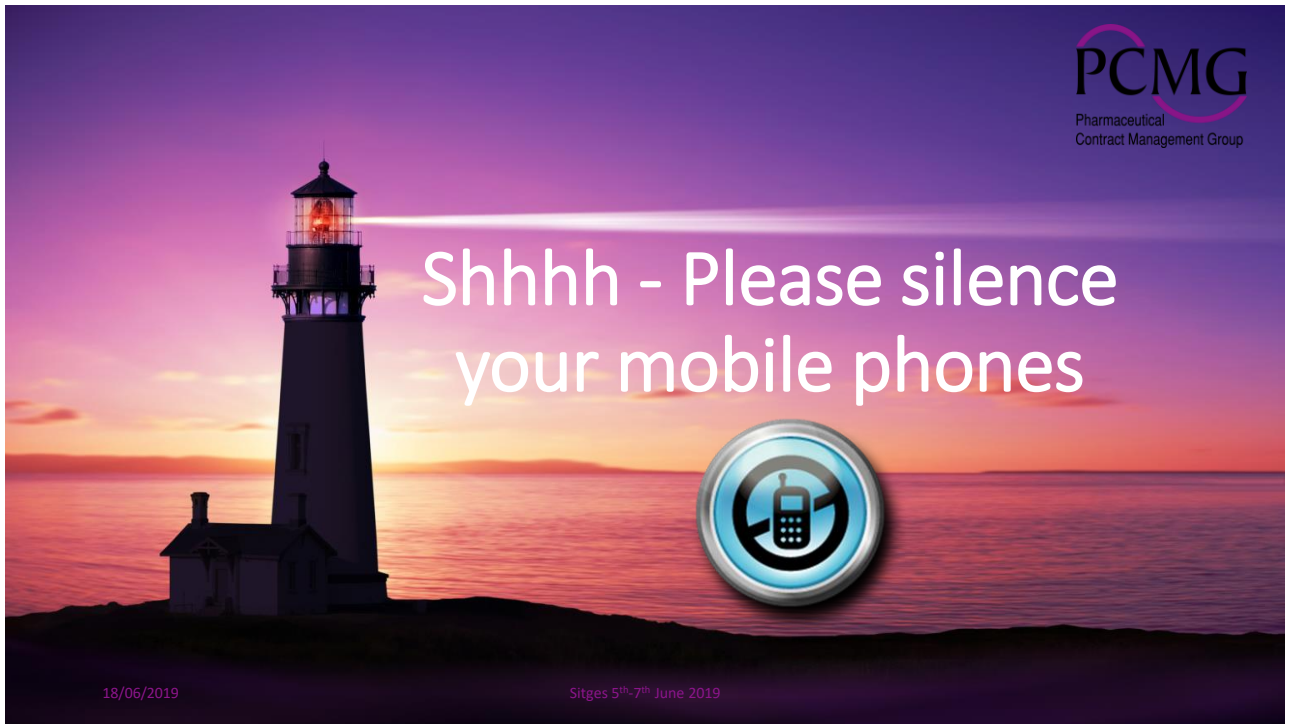
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Sitges 5th-7th June 2019

**PCMG sincerely thanks all the sponsors
who help make this event possible***



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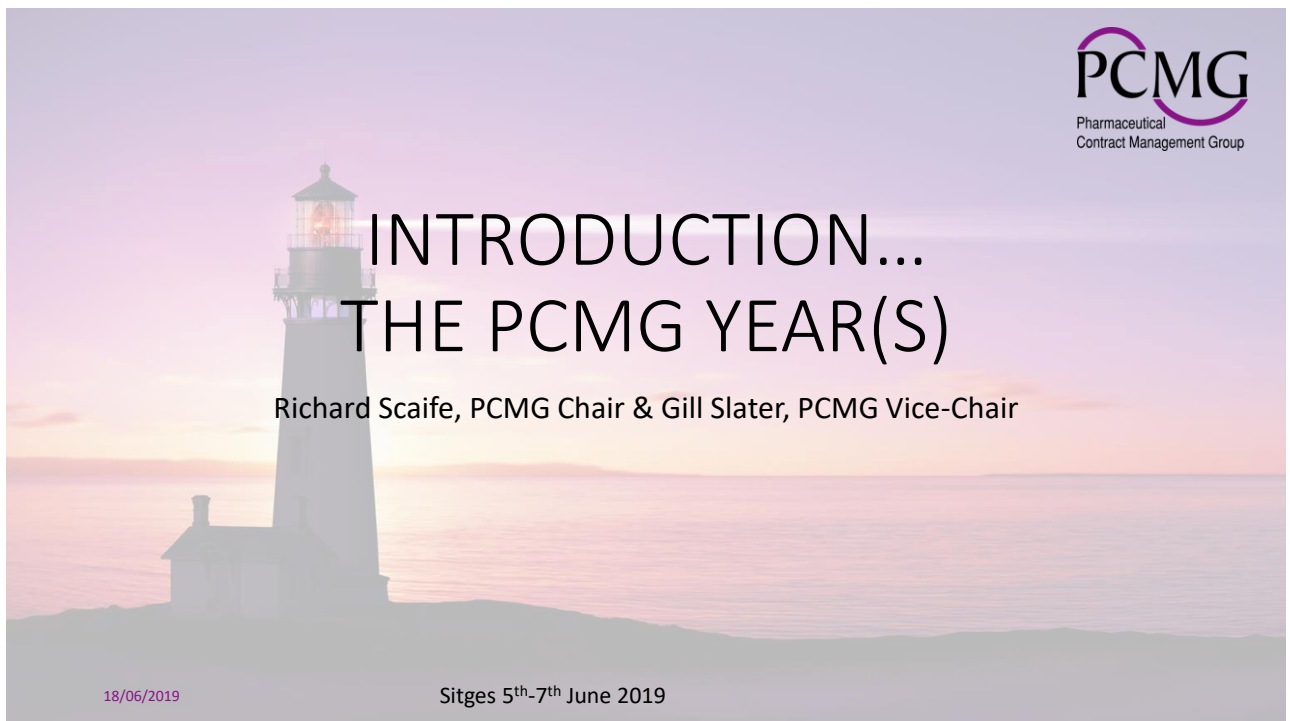


To avoid breaching any competition legislation, participants are reminded not to engage in any discussion which could be considered potentially anti-competitive. These include (but are not limited to) information regarding pricing, market shares, terms of sales, investment plans, individual terms of business or any other action which may restrict competition. Participants are also reminded to adhere to their company policies and should inform the organisers about any discussion which could breach their policies or the competition legislation.

Review of the PCMG year

Richard Scaife & Gill Slater

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INTRODUCTION...
THE PCMG YEAR(S)

Richard Scaife, PCMG Chair & Gill Slater, PCMG Vice-Chair

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Sitges 5th-7th June 2019

Consistency
Continuity
Consolidation
Collaboration
Change
Complexity
Competency

The 2019 Steering Committee

David Webber	Jean Edwards
Dorothee Walter	Birant Osman
Sandra Johnson	Ray Collia
Natalie Fforde	Mike Ryan
Steve Roan	Rob Aitchison
Graham Belgrave	Mark Bee
Dan Nicholson	David Davies

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The Outsourcing Environment
Working with Academia
Delivering results
Big Data
Device Development & Outsourcing
Interactive Session Good News/Bad News
Lifetime Achievement Award
Managing outsourced studies in Japan
Patient Centricity
Procurement from another angle

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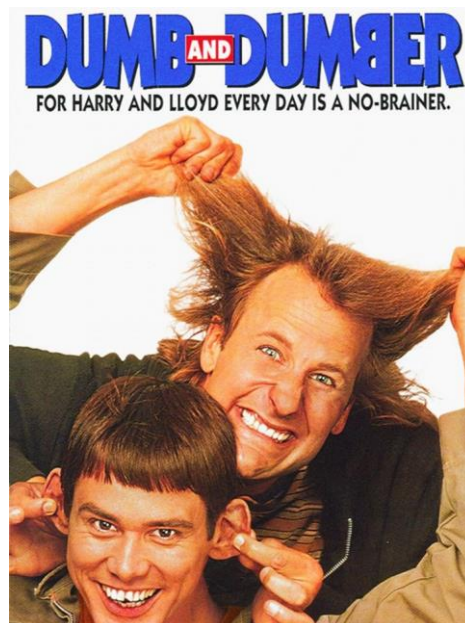
1994.....

A group of Pharma contract managers met in Zeneca's offices in London. How could the industry better harness the expanding Contract Research Sector?





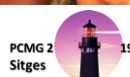
25 Years
Later....?



PCMG
Pharmaceutical
Contract Management Group

Life
Imitates
Art?

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THE THREE BREXIT ISLAND MONKEYS



SEE NO BREXIT PROBLEMS

HEAR NO BREXIT PROBLEMS

SPEAK NO BREXIT PROBLEMS

PCMG
Pharmaceutical
Contract Management Group

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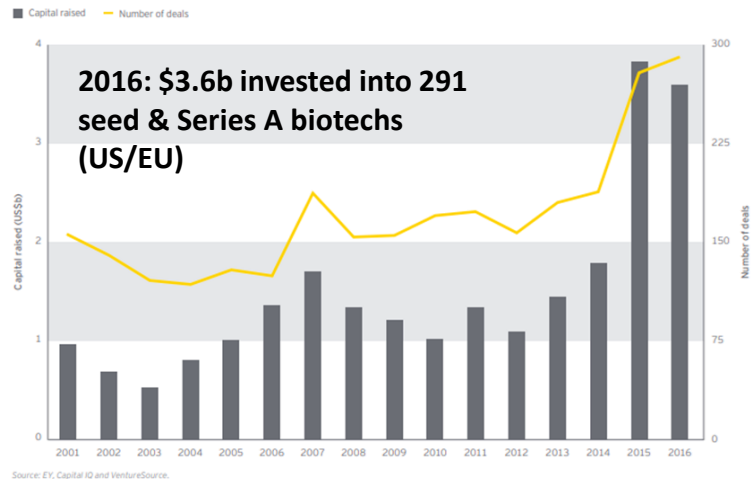
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Overview and Discussion

- Environment
- Control
- Finance
- Technology

US and European early-stage venture investment



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Overview and Discussion

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Overview and Discussion

Strategic Partnerships Accelerate Development



- Environment
- Control
- Finance
- Technology

R & D / Venture	In-License/Other	Co-Development/ Co-Promotion	Acquisition
 California Life Company MD Anderson Cancer Center accelerator CALIMMUNE eFFECTOR ALECTOR MORPHIC artios exicure Seattle Genetics gmi ZEBRA pureMHC	 CYTOMX argenx C2N BIOARCTIC NEUROCRINE Moderna apogenix synlogic DONG-A ST Voyager Calibr mission Therapeutics TIZONA LUPIN PRINCIPIA	 Boehringer Ingelheim Genentech Bristol-Myers Squibb Pfizer Eisai ENANTA Johnson & Johnson	 Stemcentrx pharmacocyclical Facet Biotech immuven BASF Pharma KNOX

abbvie Note: Slide represents select examples only

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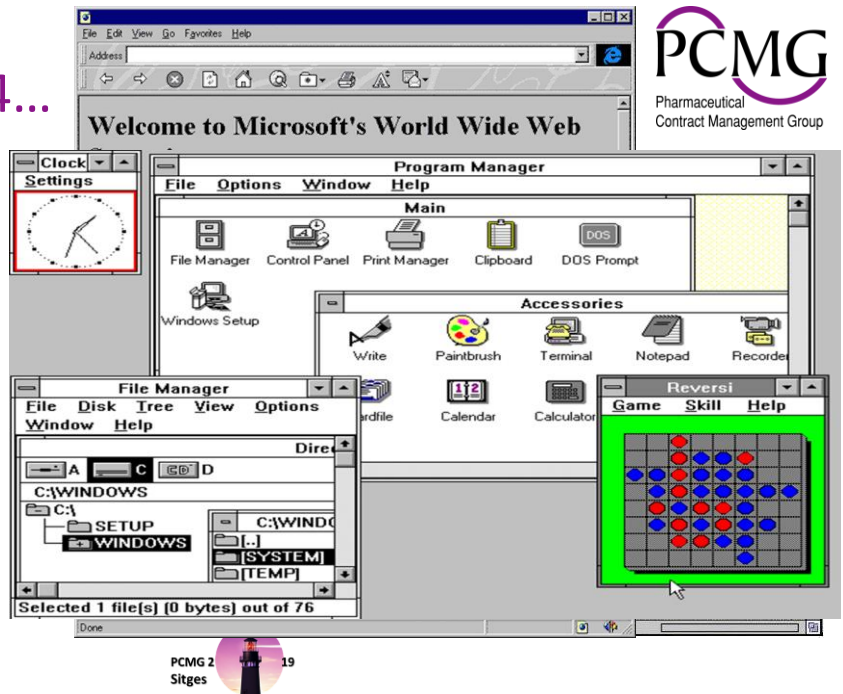


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Big Data 1994...

- Phase Forward Inform still three years from foundation and Medidata another two...
- Optical Character Recognition was State of the Art for RDC
- IBM PCs were still using the Windows 3.1 system
- Faxes and Typing Pools still led IT



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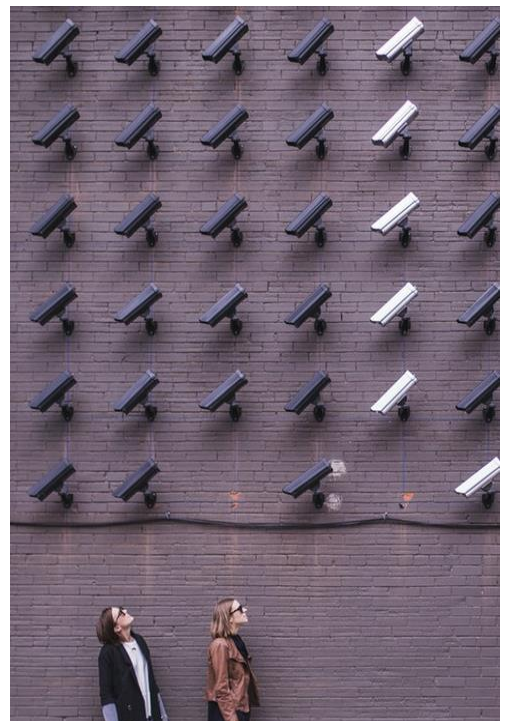
Big Data Now...

- Registries
- Who owns 'you'?
- Internet of everything..everywhere?
- Wearables or Unbearables
- GDPR protection or confusion
- 20th vs 21st Century..

'The digital revolution has largely bypassed the NHS, which, in 2017, still retains the dubious title of being the world's largest purchaser of fax machines.'

DeepMind Health Independent Review Panel Annual Report July 2017

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Big Data Now...

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- 20th vs 21st Century..

'50 petabytes of data were generated, on average, by each (US) hospital in 2018; less than 3% were put to use.'

https://www.ey.com/en_gl/life-sciences/building-a-better-working-world-in-life-sciences

'I'd be much more pessimistic about the way the world is going to go if I didn't know there was something as game-changing as AI on the way''Either we need an exponential improvement in human behaviour or an exponential improvement in technology, and the world doesn't look like it's getting its act together on the former.'

Dr. Demis Hassabis Co-founder and CEO, DeepMind (alphabet)

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Japan and Clinical Development

- Negotiation underway for ICH adoption (1997)
- Duplicate product development required
- New drug accreditation required 'Shonin' (Safety/Efficacy) **and** 'Kyoda' (Manufacturers Licence) until 2005
- Out-Licensing deals & Co- licensing/marketing
- Mergers to come:
- Partnerships & Collaborations
 - TAP 1977-2008

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Japan and Clinical Development

- Japan Pharma Market \$84b (10% global market)
- 'Abenomics' drive for external investment?
- PMD Act 2014 – faster approvals?
- Generics goal 80% volume by April 2020
- Cost-effectiveness assessment
- Takeda & PRA Joint Venture in Japan
 - .. the emphasis on value and outcomes will continue to secure a place for innovative and differentiated products in Japan.***

McKinsey Aug 2018

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Patient Centricity

- A new role in the food chain
- Orphan/Niche Treatment



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The PCMG Year



February: Conflict Management & Resolution Workshop

April: GDPR Workshop

May: Outsourcing Essentials Training Course

Ongoing: PCMG Forum - Sharing Best Practice

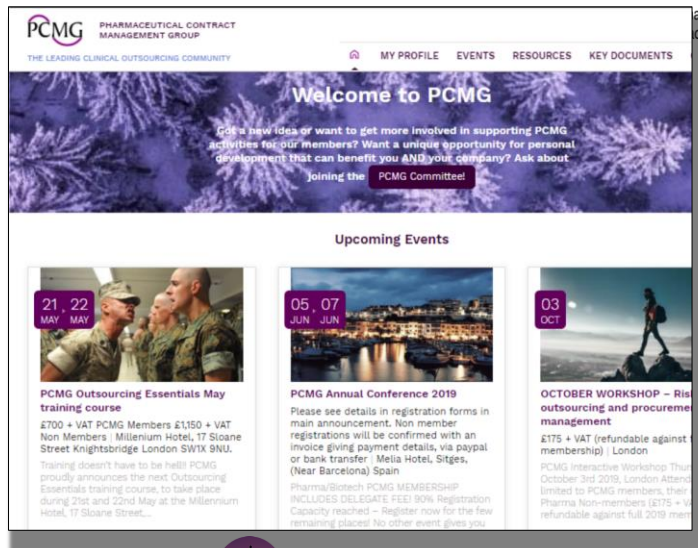
October: Managing Risk Workshop

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Website is LiVe!

Where you will
find....



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**ADVANCED
Outsourcing
Essentials
Training
Course
London
22/23
October
2019**

THIS IS
THE SIGN
YOU'VE BEEN
LOOKING FOR

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And finally..... 'Children of the Magenta'?



"We appear to be locked into a cycle in which automation begets the erosion of skills or the lack of skills in the first place and this then begets more automation."

Warren Van Der Burgh. 14x Top Gun & AA Captain



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