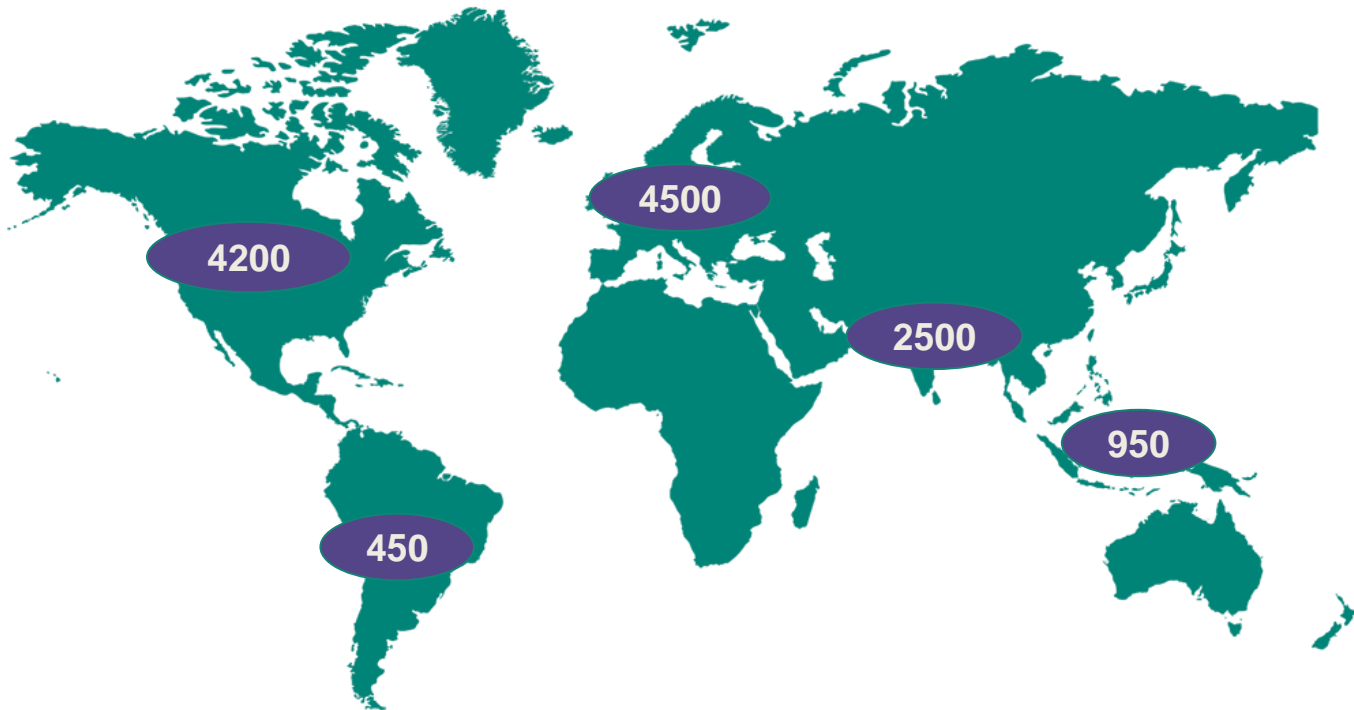


**How to foster transformative learning that is sympathetic to scientists' conflicting priorities. Training "on the job" or "for the job" – a dilemma?**

Peter Schüler, MD  
SrVP Drug Development Services CNS  
ICON Plc



# ICON - A Global CRO with over 12 600 employees



**Operating from 81 offices in 39 Countries**  
**All Training has to be globally consistent**

# ICON Overview - Full Service Solutions

Service areas for all aspects of drug development

## Commercialisation & Outcomes

- Peri-approval & Observational Research
- Pricing & Market Access
- Health Economics
- Language Services
- Scientific Communications

## Medical Imaging

- Central Reading Solutions

## Laboratory Services

- Central Laboratories
- Immunoassay
- Biomarkers

## Consulting Services

- Strategic Clinical Development
- Chemical & Manufacturing Controls (CMC)
- Business Process Improvement

## Early Phase Services

- Clinical Pharmacology
- PK & Biostatistics

## Clinical Research Services

- Phase II-III Clinical Trials
- Project Management
- Clinical & Data Operations




## Resourcing & FSP Services

- Functional Service Provision
- Program Insourcing
- Permanent Hiring Solutions



## Background

### *What the people want – 2014 ICON Medical & Safety staff survey (n=350)*

<b>Group: Country</b>	 % Fav	 % Neut	 % Unfav
Schueler, Peter_ICR Medical & Safety Srvs	52	28	20
Argentina	30	43	27
Germany	31	33	36
India	69	21	10
Japan	45	42	14
Mexico	64	32	4
Philippines	87	13	
Poland	57	29	15
Singapore	38	27	35
UK	36	38	26
US	45	27	28

## Method

### *Three different alternatives for training compared*

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1. A two years post-graduate MSc course in Pharmaceutical Medicine at University Duisburg-Essen, accredited by IFAPP and IMI Pharma Train Center of Excellence
2. A eight months accredited training program “Drug Safety Academy”, developed by ICON in collaboration with International Academy of Clinical Research (IAoCR), UK
3. A six weeks Project Management course, developed by ICON in collaboration with the International Institute of Learning (IIL) and evaluated by Corporate Executive Board (CEB)

# Example 1: The University Duisburg-Essen Master Course

- Postgraduate study course
- 2 years program duration
- 19 course units, 3 days each
- Course language English
- 14.850€ for full two years plus travel expenses

<b>Characteristics of the students</b>	
Number of students	230
Mean age (in years)	34
Gender (m/f)	51/49
Overall average final grade	1.8
Second Degree („Doctor“)	51 %
Third Degree („Professor“)	7 %

# The University Essen-Duisburg Master Course

2005 Accreditation and state recognition



2007 Accreditation, international recognition

International Federation of Associations of Pharmaceutical Physicians (IFAPP)



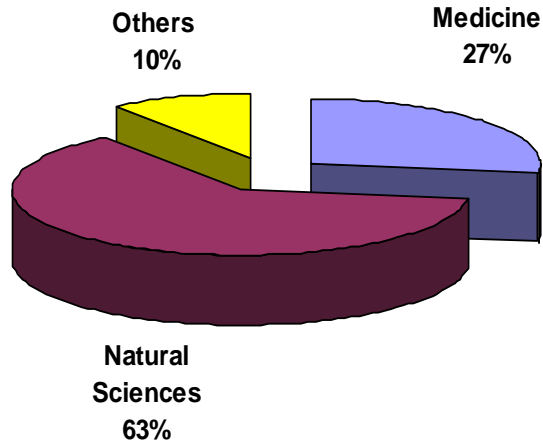
2012 IMI PharmaTrain, Centre of Excellence



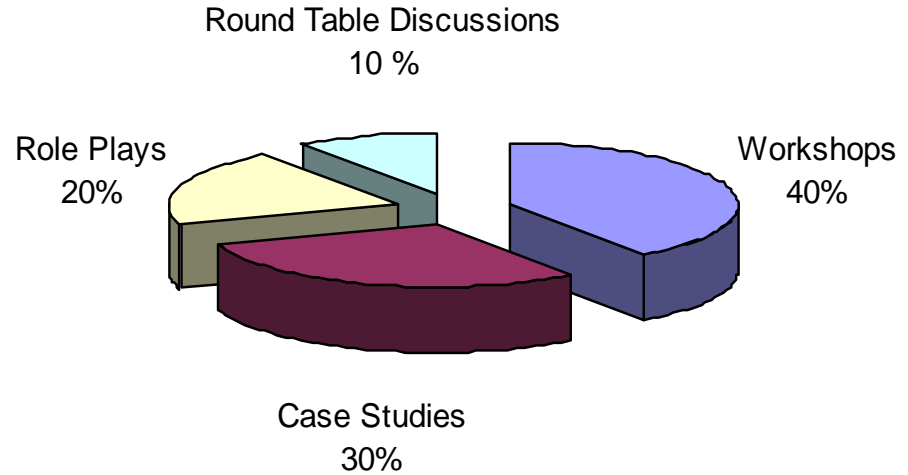
European Curricula  
for Global Expertise

# The University Essen-Duisburg Master Course

## Professional Qualification



## Didactic Methods



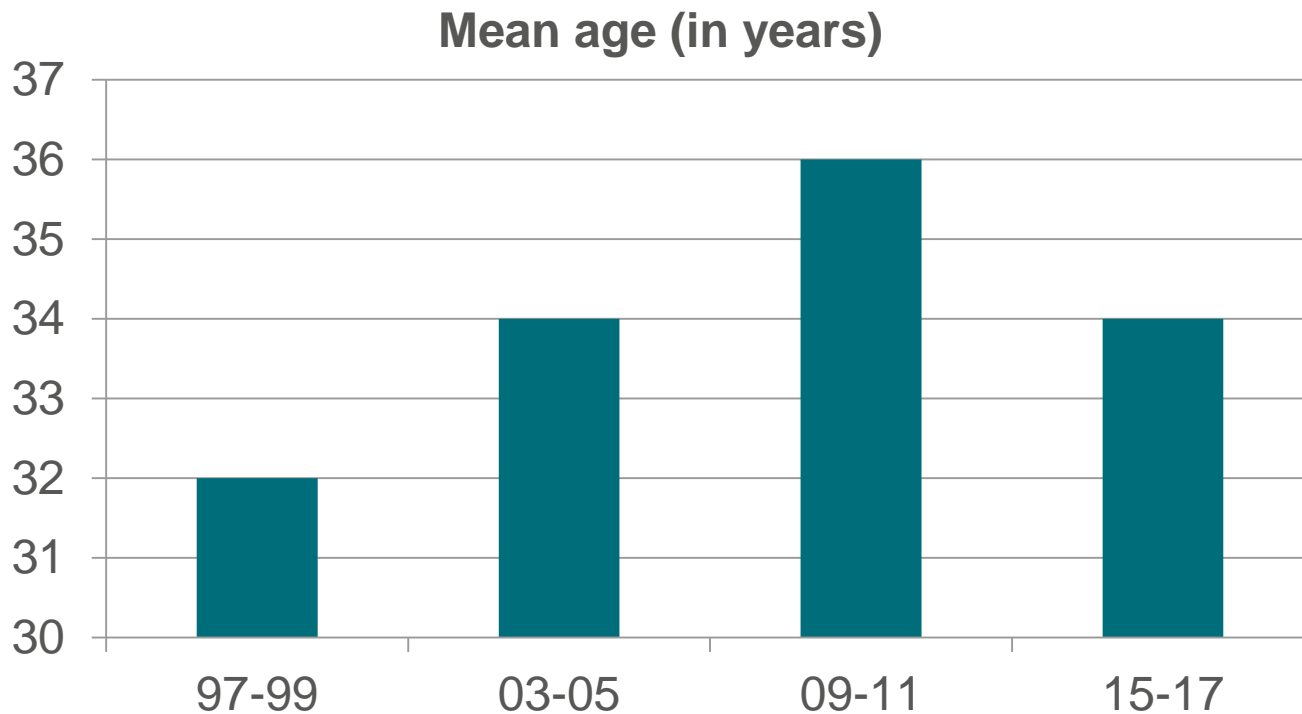
All face to face



## Results

### *Master Course – less interest by more mature staff*

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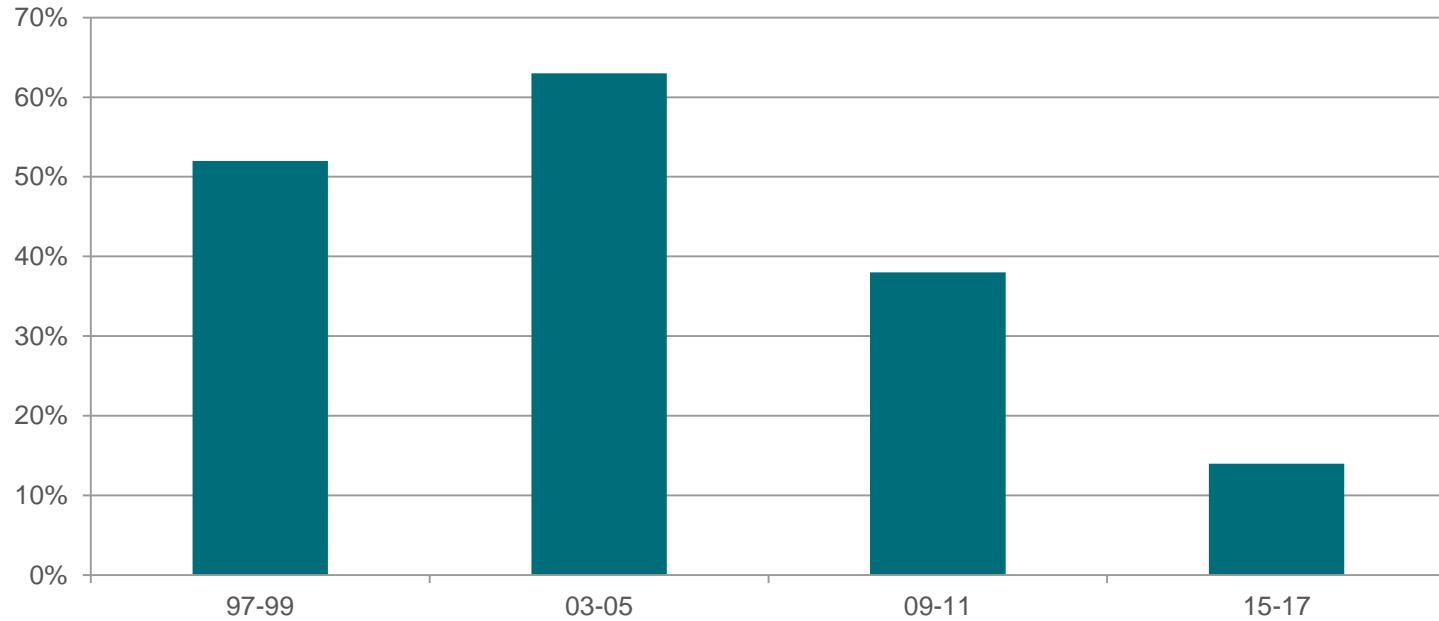


# Results

## *Less interest amongst the more educated*

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### Second Degree („Doctor“)

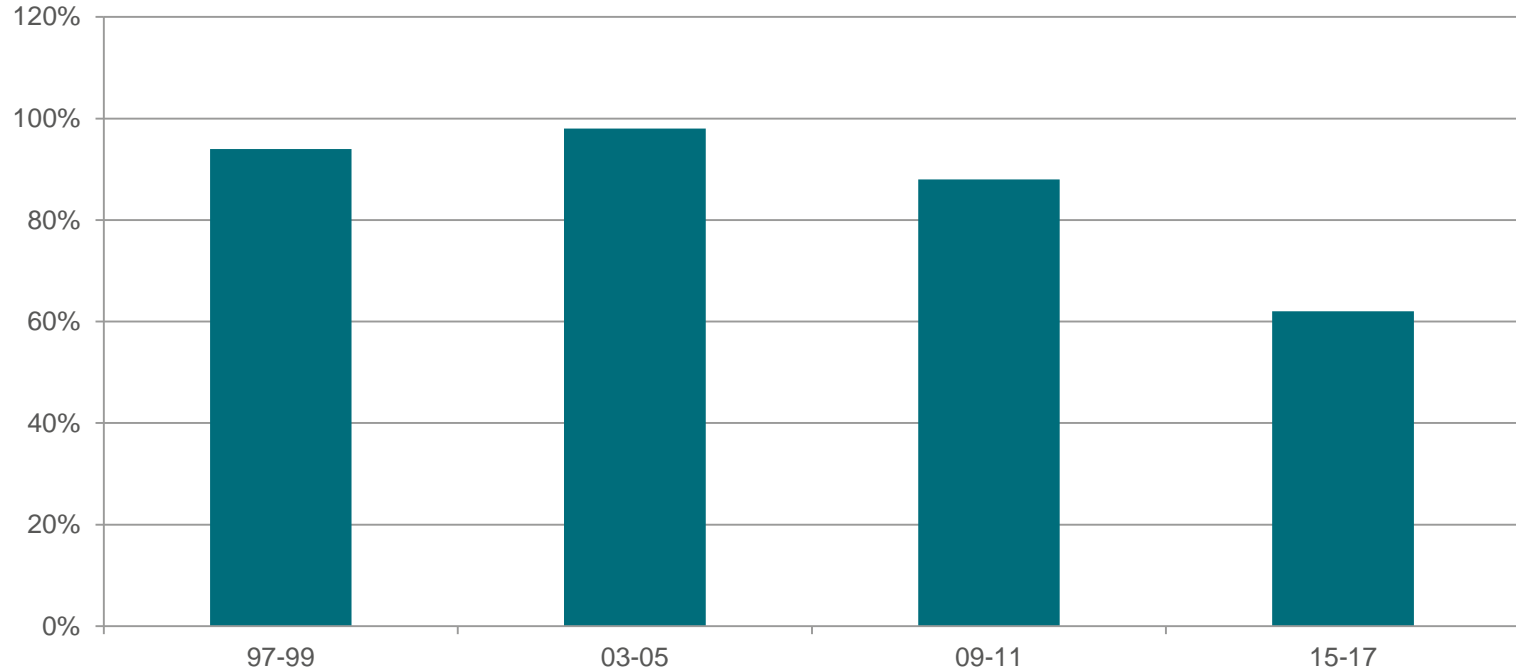


# Results

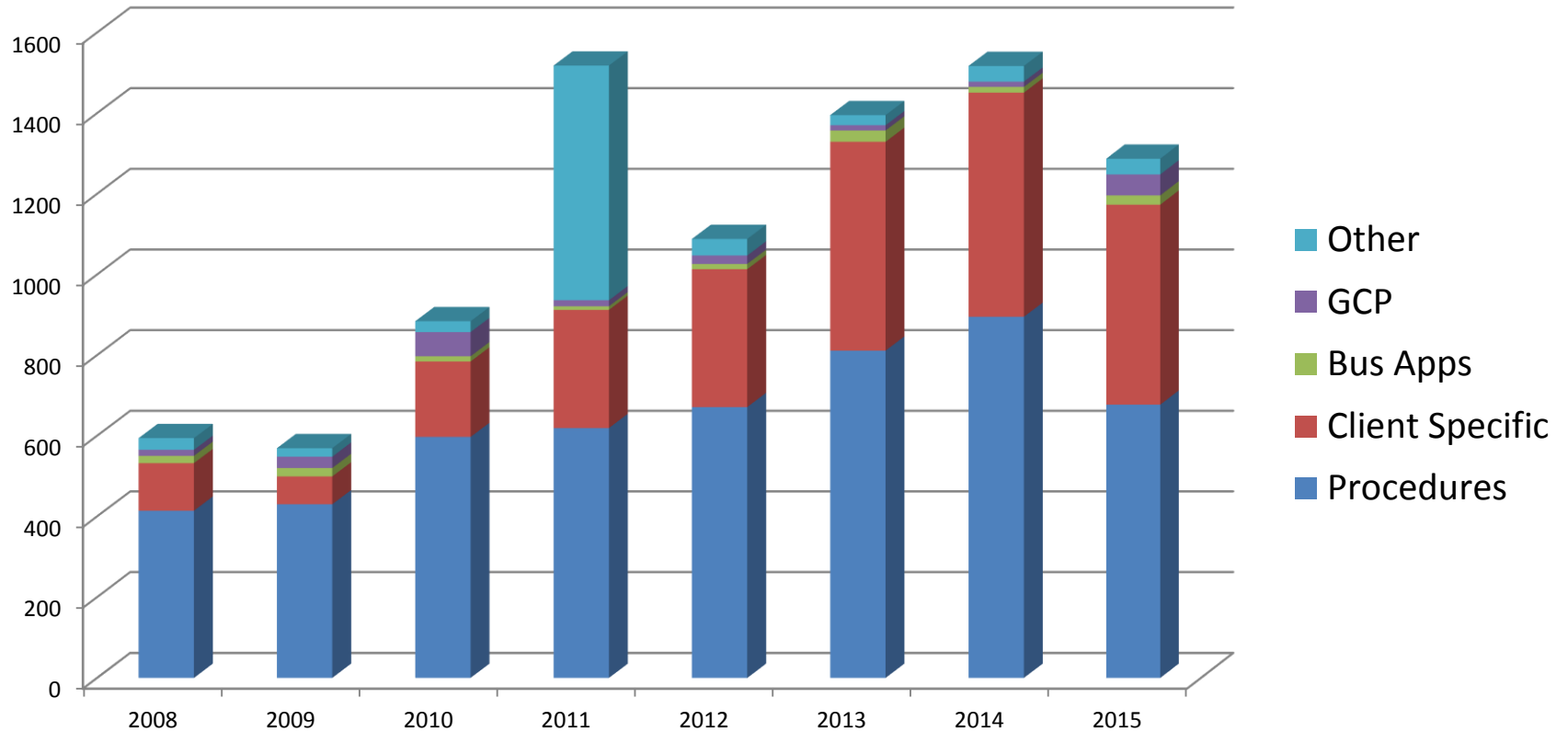
*Became the work environment too condensed in past 20 years?*

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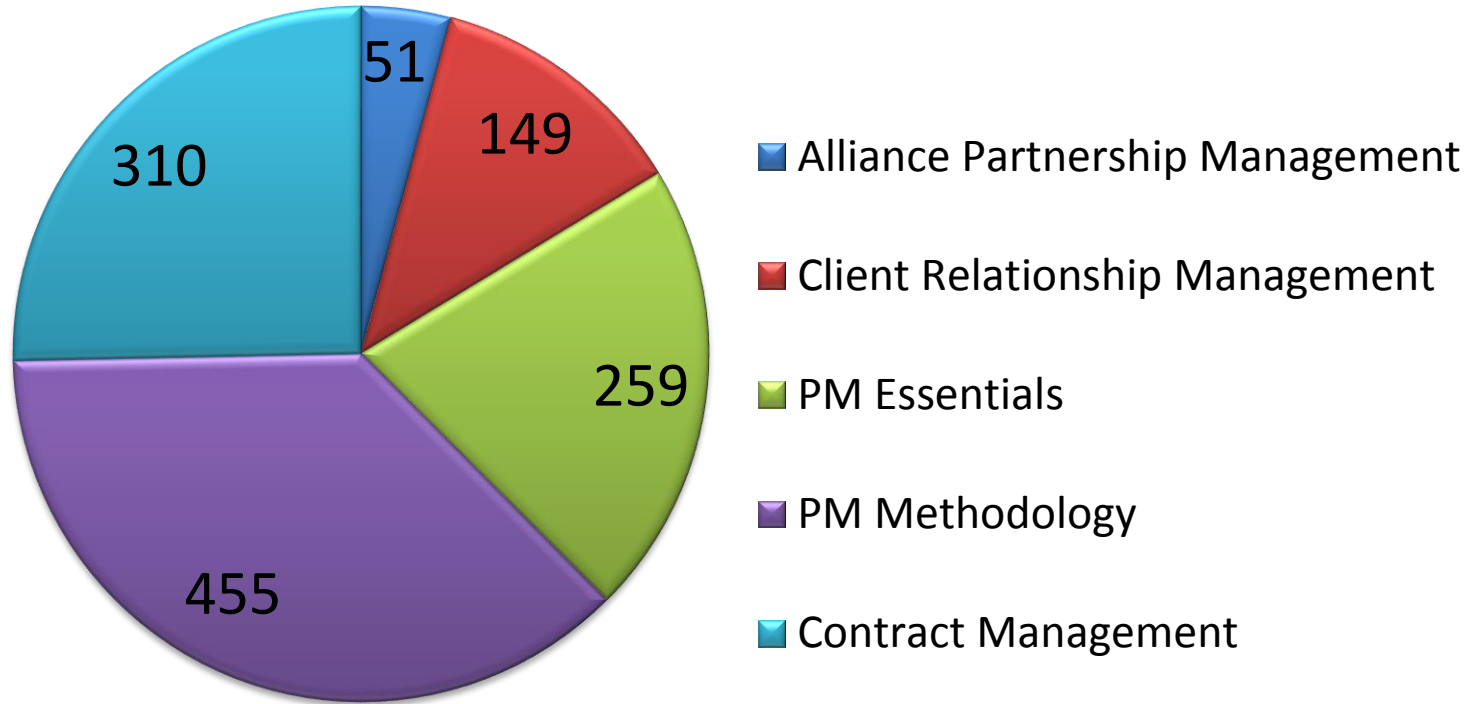
## Participation while the participant is working



## Example 2: The ICON Internal Training – Attendees 2008 - 2015



## Example 2: The ICON Project Management Training – Attendees 2015



## Results

### *Reasonable costs per participant*

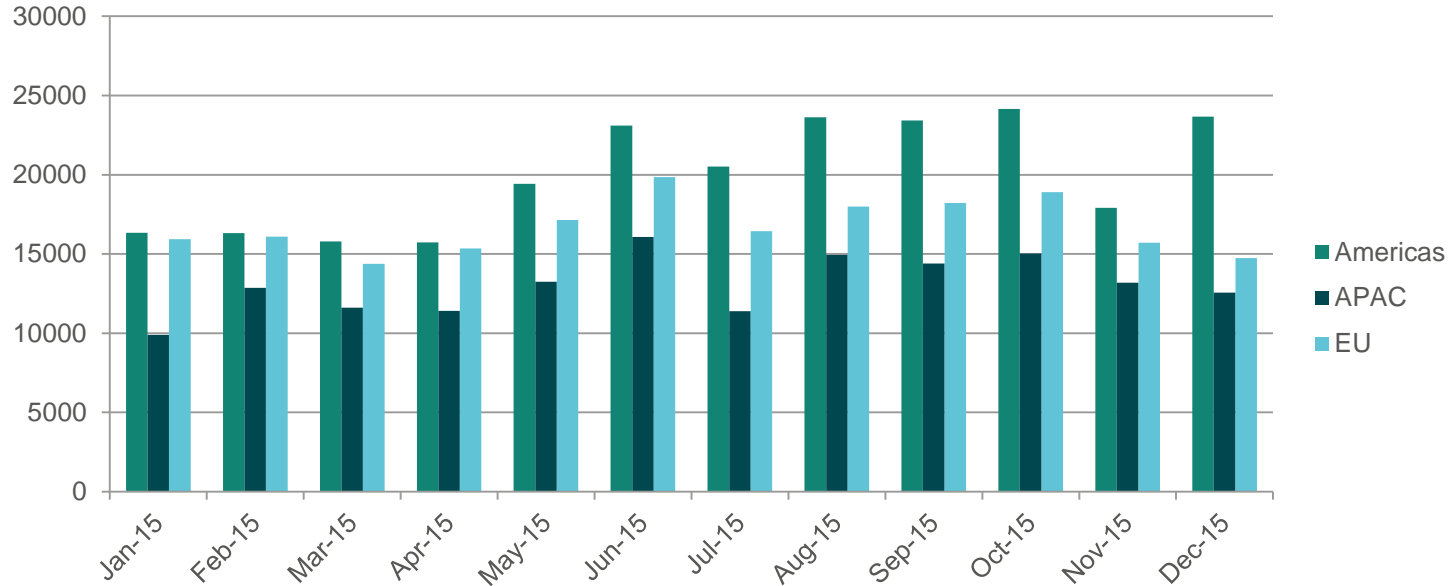
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<b>Program</b>	<b>Number of course in the Program</b>	<b>Total Number Sessions</b>	<b>Total Number of Attendees 2015</b>	<b>Direct Costs per Attendee</b>
PM Essentials	3	19	259	\$2498.47
Client Relationship Management	5	14	149	\$1560.70
Alliance Partnership Management	3	4	103	\$2204.76

# Results

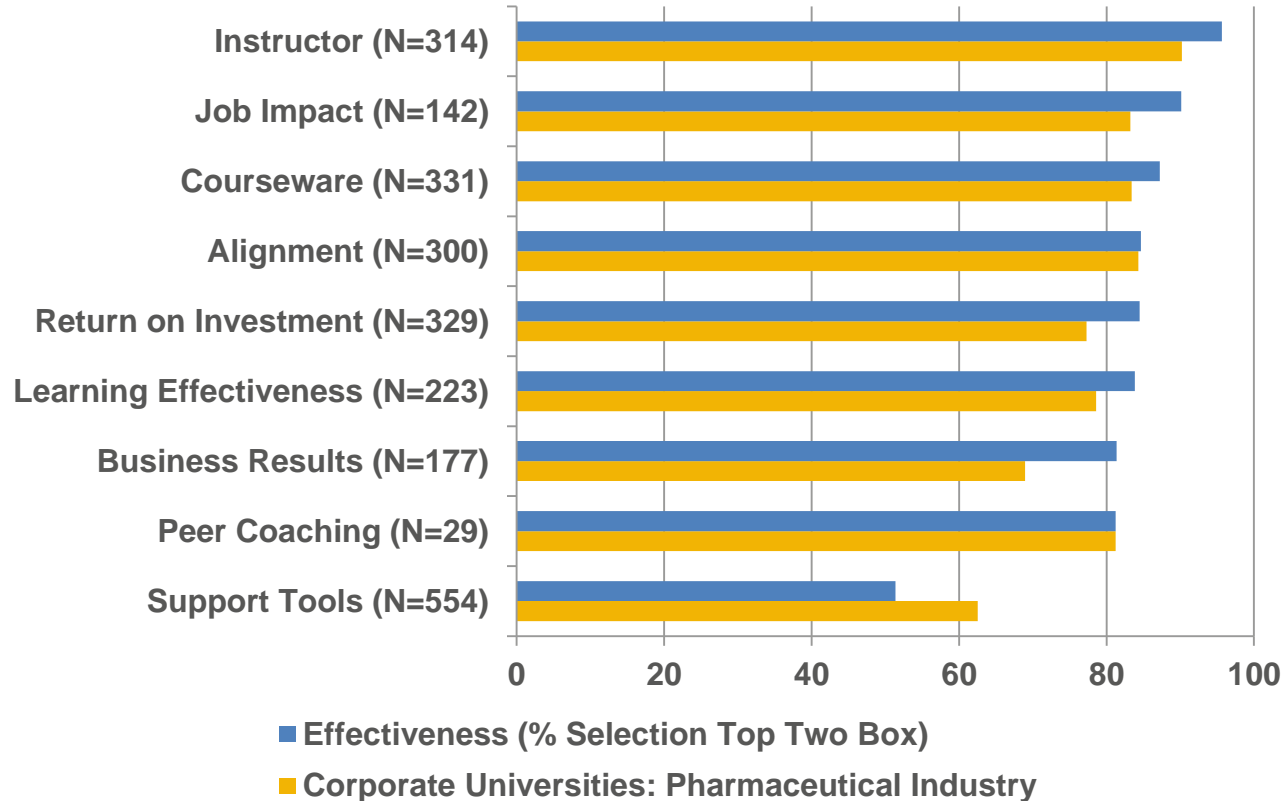
*Stable participation throughout the year*

## 2015 Total OLL Courses Complete by Region



# Results

## *Positive feed-back and Industry average*





# Results

## Positive feed-back with impact on performance

### Predicted Performance Improvement



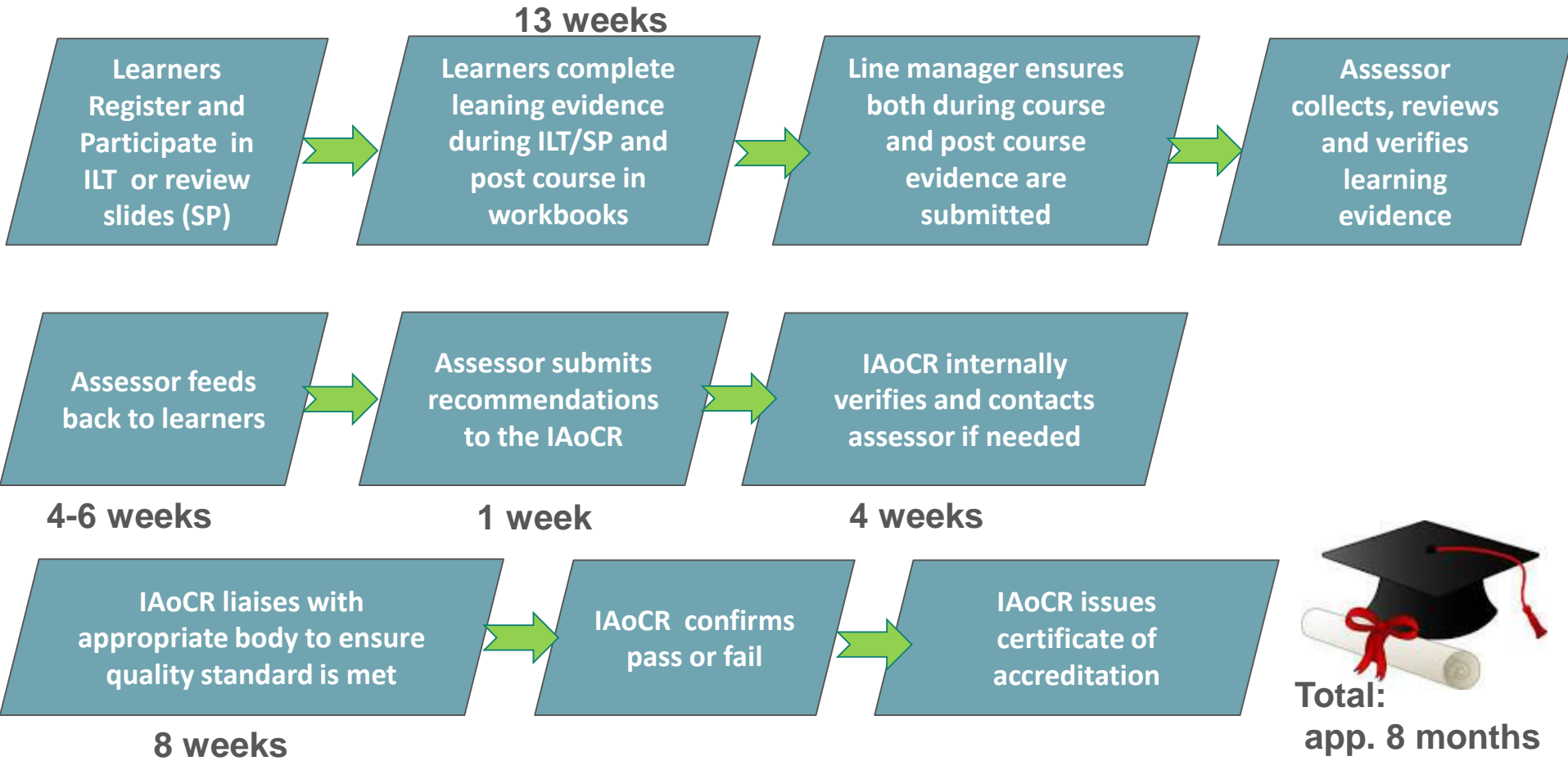
Learners *estimate* that their performance improved by more than half after training and that roughly 57% of that improvement was *due to training*. Participants, on average, believe the knowledge and skills are relevant to 74% of their *work time*. When we combine these values by multiplying them together and adjusting them by response bias, we get a conservative estimate of **predicted performance improvement: 15%**.

Factor	Item	Amount
Estimate	Estimate how much you expect your job performance related to the course subject matter to improve in the next 12 months. Include in your estimate any performance improvements due to this training, as well as all other factors like on the job experience, incentives, and process improvements.	54%
Isolate	Based on your response to the prior question, how much of the improvement will be a direct result of this training, as opposed to other factors?	57%
Isolate	How much of your total work time requires the knowledge and skills learned in this training?	74%
Adjust	An adjustment for response bias, confidence, and conservatism.	65%

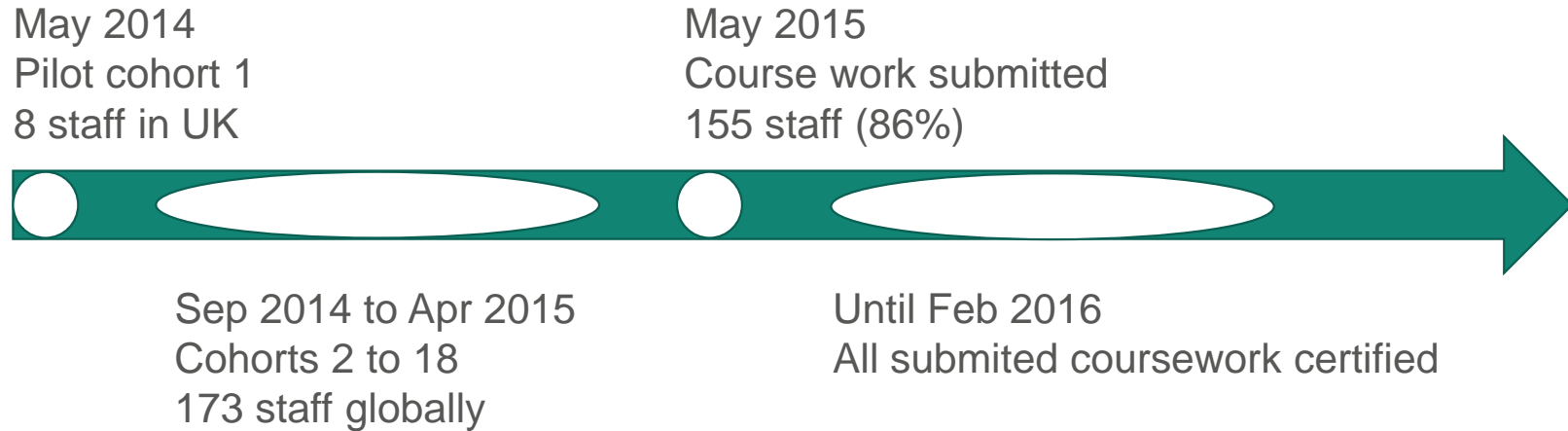
# Example 3: The ICON Safety Associate Certified Course

Title	Content
<b>M1: Background and Origins of Pharmacovigilance</b>	<ul style="list-style-type: none"><li>• History of Pharmacovigilance</li><li>• Drug development e.g. phase I-IV clinical trials associated regulations</li><li>• Lifecycle of Clinical Trial</li></ul>
<b>M2: Sources of Safety data and how they are managed</b>	<ul style="list-style-type: none"><li>• Overview of sources and detection of different types of safety signals including : SAE, AEs, ADRs, spontaneous Report, Overdose, pregnancy and other (Literature Cases, CA reports, Call Centre- medical information, PQCs, lab - DILI, CRF, Endpoint review)</li><li>• How these safety signals are managed</li></ul>
<b>M3: Event Reporting and Regulatory Requirements</b>	<ul style="list-style-type: none"><li>• SUSAR reporting (Triaging, expectedness, relatedness, day zero, timelines)</li><li>• Reporting requirements</li><li>• Periodic reporting</li></ul>
<b>M4: Case Processing, Query Management and Narrative Writing</b>	<ul style="list-style-type: none"><li>• Roles and responsibilities of different parties (e.g. reporter, Clinical team)</li><li>• Steps of case processing, ensuring valid case, serious criteria definitions, grading, medical review, fundamentals of effective query raising</li><li>• Format and structure of safety narratives</li><li>• Different types of narrative</li></ul>
<b>M5: Role of Electronic Data Capture, Tools and Systems</b>	<ul style="list-style-type: none"><li>• Safety database role and function, do we always need one</li><li>• Clinical EDC role and function, SAE reconciliation</li><li>• Lab vendors, collection repositories</li><li>• Safety reporting portals</li></ul>

# Example 3: The ICON Safety Associate Certified Course



## Example 3: The ICON Safety Associate Certified Course



- 8,500€ annual base fee plus 450€ per certified student plus internal investment of 1.5 FTEs for 5 HC trainers and one coordinator
- Total 1.710€ per each completer
- 6 credits for job competency at EQF Level 3

# Results

## *Significant time-investment*

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### **Trainers (5) 216 hours**

2 EU - 48hrs

1 US - 24hrs

2 AsiaPac - 144hrs

### **Admin(1) 562 hours**

2 days per week Sept-2014-May2015 = 75 days

### **Assessors (6 in total) 1,125 hours for 173 candidates**

2-4hrs review round 1

1-2hrs review round 2

0.5hrs review round 3

### **Candidates (173) 12,456 hours+**

# Results

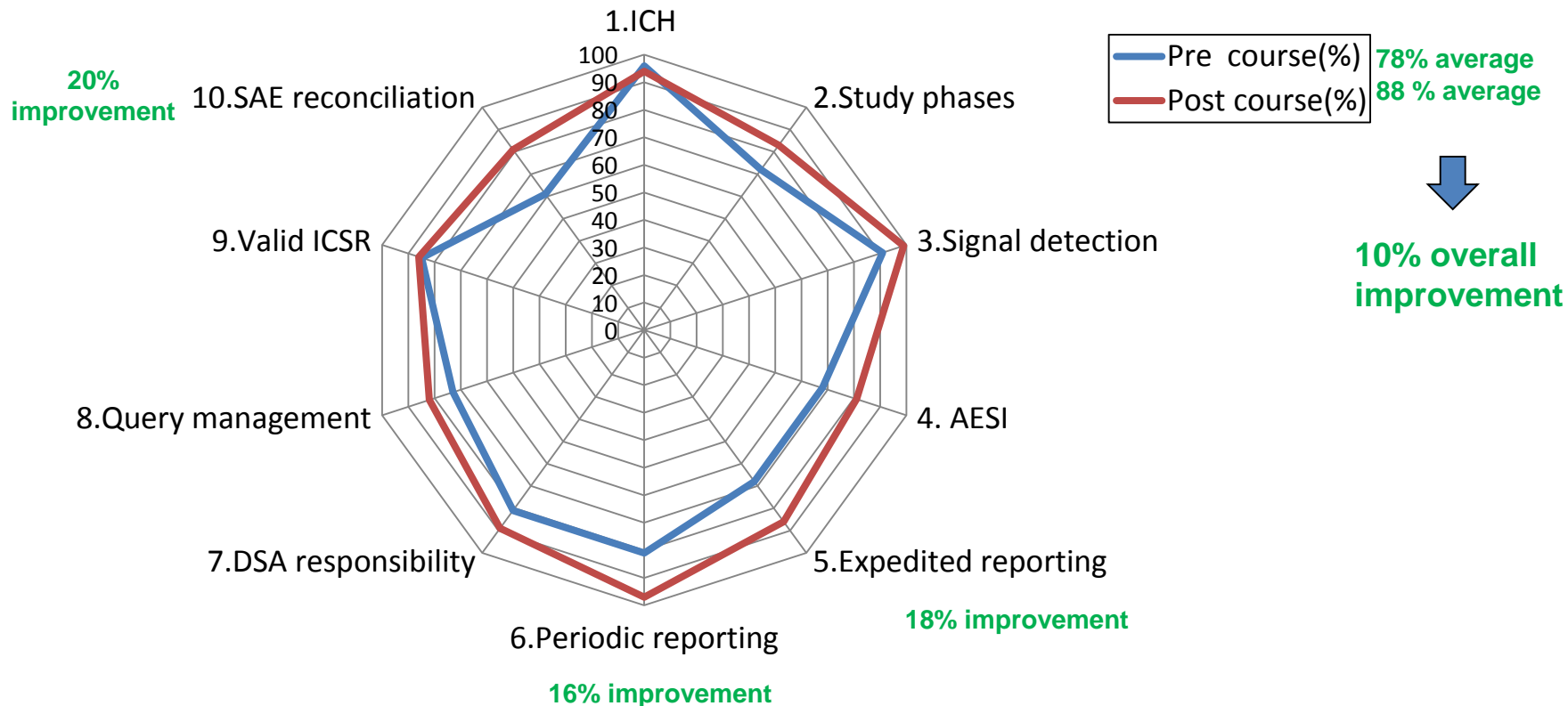
*Self rating of competence on scale 1 to 5 (rounded)*

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Module 1 Understanding PV	Module 2 Sources of safety	Module 3 regulatory reporting	Module 4 Case processing	Module 5 Data bases	Overall Course Meets your needs
3 -> 4	3 -> 5	3 -> 4	3 -> 5	3 -> 4	4

# Result

## Assessment of competences with impact on performance



## Result

### Some Feed-Back

---

*Every session had something new for me to learn*

*Content and materials were helpful and further reinforce different aspects of the modules content*

*I could learn other activities like regulatory reporting, query management etc., which are not my normal day to day responsibilities*

*Presentation methods interactive, especially through the whiteboard and polling*

*Very time-consuming*

*Not easy to implement in daily activities*

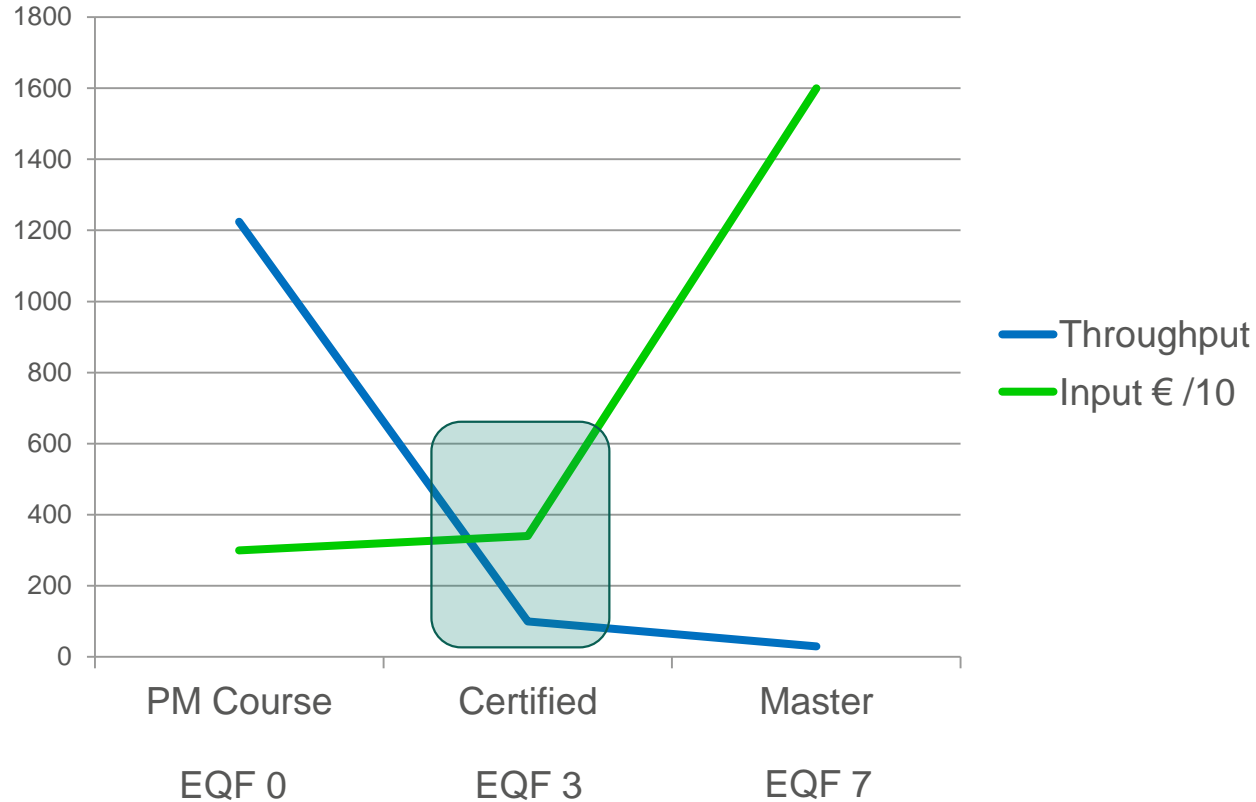
*It took very long from registration to final certification*

*I was also trained on aspects not necessarily relevant for my daily routing*

*What di the credit points men for me?*



# Summary: Optimize Input against Output



# SWOT for Certified Competency Training

## Strength:

- Highly cost-efficient
- Targeted content
- Global
- Staff retention

## Weakness:

- Limited throughput
- Need for competent trainers and raters
- No regional adaptation
- Low impact of Credit Points (6)
- Long duration & upfront investment

## Opportunities:

- Expand in other Job Roles
- Depends on few staff
- Stronger weight and / or better process of accreditation

## Threats:

- Need for competent trainers and raters
- No acceptance of credits
- Staff as hiring target



**Thank you for your  
time and attention**

ICON plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. ICON currently, operates from 81 locations in 37 countries and has approximately 11,300 employees.

[ICONplc.com](http://ICONplc.com)

