

PAASPort

a tool to identify data quality in
biomedical research



Partnership for Assessment and Accreditation of Scientific Practice

Heidelberg, Germany

www.paasp.net

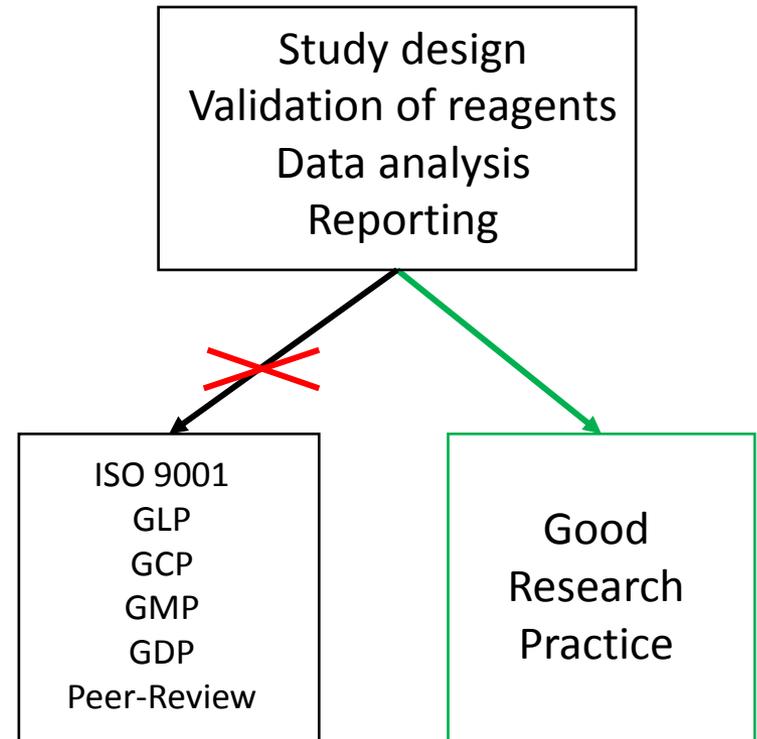
Assessment of Good Research Practice

Editorial on Retraction Watch (Feb 4th, 2016) by Amy Lossie (NIH) and Viraj Mane (Consultant)

Do Scientists need audits?



“...around 1% of taxpayers faced an audit last year. However, this low risk of audit still keeps tax code violations down to around 17% of filings. ...”



An evaluation protocol could bring benefits to research

<http://retractionwatch.com/2016/02/04/do-scientists-need-audits/>

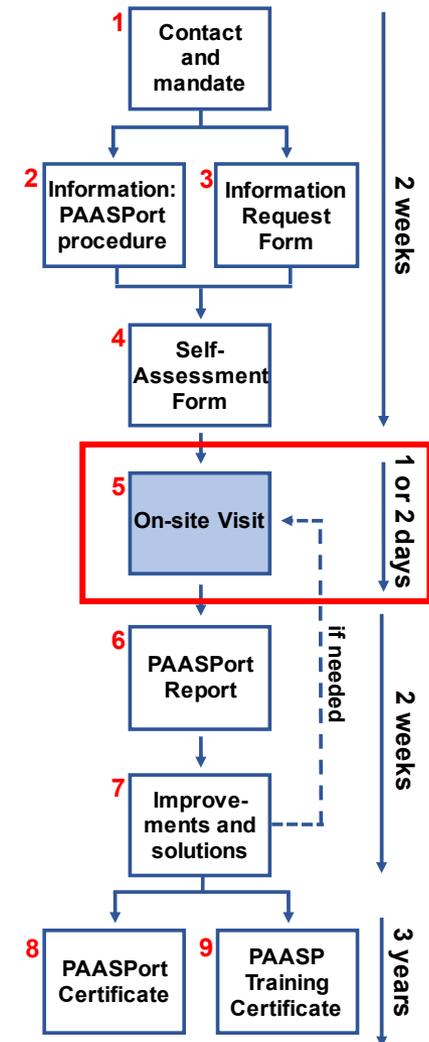
PAASPort: Build Confidence in Data

All potential sources of bias are addressed

- Related to study design, data analysis, personnel, competition, financial and organizational (200+ questions)
- **Research quality separated from science**
- Third-party view

Fast and efficient workflow

- Preparation phase
- On-site evaluation
- Recommendations and discussion



PAASPort evaluation: The matrix

	Protection Value	Rating	Findings (numbers and pull-down menus)	Findings (free text)
Study design				
- Blinding	0,43			
blinding procedure	1		Full	
when is the blinding broken	1		Appropriately	
unblinding controlled	0		Aware but not controlled	
impact of unplanned unblinding	0		Risks unclear	
positive controls included in blinding	1		Yes	
emergency scenarios foreseen	1		Yes	
overall attitude towards blinding	-1		Negative	
verified	2		Mostly not confirmed	
Randomization				
typical	1		Proper randomization	
procedure	1		Integrated with blinding	
exceptions	1		Accepted but not defined	
understanding of importance	0		Not clear	
verified	2		Mostly not confirmed	
- Pre-specified endpoints				
Primary dependent variable explicitly stated	1		Yes	
Safely recorded	1		Yes	
Data analysis methods pre-defined	1		Yes	
verified	2		Mostly not confirmed	
- Power analysis				
post hoc	1			
a priori	1			
done by whom?	0			
documented?	1			
verified	2			

Yes	Partially	Mostly not confirmed
0,5	1	2

Full	Partial	None
Appropriately	Risks unclear	Too early
Checked and reported	Aware but not controlled	Not aware
Minimal impact	Risks unclear	Can affect analysis/reporting
Yes	No, but justified	No
Yes	Not clear	No
Positive	Not clear	Negative
1	0	-1

Proper randomization	Pseudo-randomization	None
Integrated with blinding	Appropriate tools	Questionable tools
None	Properly defined	Accepted but not defined
Good	Not clear	Lacking
	0	-1

Yes	Not clear	No
1	0	-1

	Protection Value	abused by anyone
Study design		
- Blinding	0,43	
blinding procedure	1	
when is the blinding broken	1	
unblinding controlled	0	
impact of unplanned unblinding	0	
positive controls included in blinding	1	
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overall attitude towards blinding	-1	
verified	2	

The PAASPort matrix gives an unbiased view of the research lab

PAASPort evaluation: The matrix

	Protection Value	Rating	Findings (numbers and pull-down menus)	Findings (free text)
Study design				
- Blinding	0,14			
blinding procedure	1		Full	
when is the blinding broken	1		Appropriately	
unblinding controlled	0		Aware but not controlled	
impact of unplanned unblinding	0		Risks unclear	
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emergency scenarios foreseen	1		Yes	
overall attitude towards blinding	-1		Negative	
verified	2		Mostly not confirmed	
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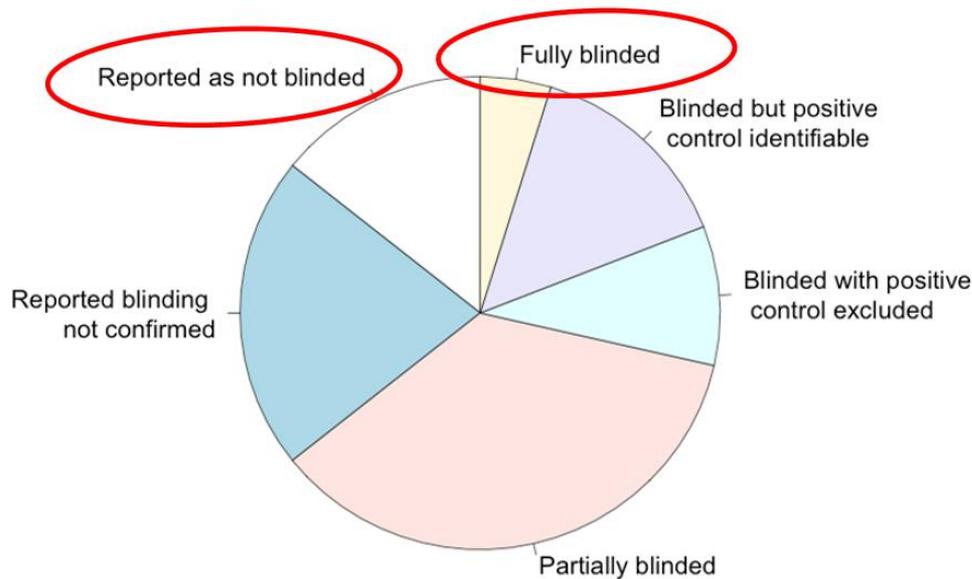
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PAASPort evaluation: Blinding as an example



Blinding in experimental pharmacology

72 experiments

- 12 academic labs
- 7 CROs
- 4 industry labs

This example revealed a large inhomogeneity for blinding

Feedback from customers

- **Customers**
 - Respond really positive due to the mutual work relationship
 - Are satisfied with the transparency of the PAASPort protocol
 - Find it helpful to have a third-party view on their research process



European-based Contract Research Organisation:
“The carefully thought-out feedback by PAASP following the assessment led us to learn about our strengths, and identify aspects in our research conduct that we could further develop.”

Further projects ...

...to establish assessment protocols and GRP guidelines

- Innovative Medicine Initiative (IMI) call on "Data quality in preclinical research and development"
- **Springer-Series** Handbook of Experimental Pharmacology: "Good Research Practice in Pharmacology and the Experimental Life Sciences"
- International Union of Pharmacology (IUPHAR) Developing guidelines for best practice in study design, data analysis and reporting
- ...



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Thank you for your
attention