Importance of registries and databases in clinical practice and research

McGill Maxillofacial Oncology Registry

Nicholas Makhoul DMD. MD. FRCD(C). Dip ABOMS. FACS.

Director, Division of Oral and Maxillofacial Surgery
Assistant Professor McGill University, Faculty of Dentistry
Chief, Department of Dentistry and Oral and Maxillofacial Surgery
McGill University Health Centre











Paradigm Shift in Health Care Delivery

Rising Costs

Budgetary Constraints Aging
Population and
chronic
diseases

Reduction of Available Resources Rising Costs

Budgetary Constraints Aging
Population and
chronic
diseases

Reduction of Available Resources

Academic/Hospital Dentistry

Rising Costs

Budgetary Constraints Aging
Population and
chronic
diseases

Reduction of Available Resources

Academic/Hospital Dentistry

Education

Quality Care

Quality Assurance Scientific Contribution



McGill Maxillofacial Oncology Registry

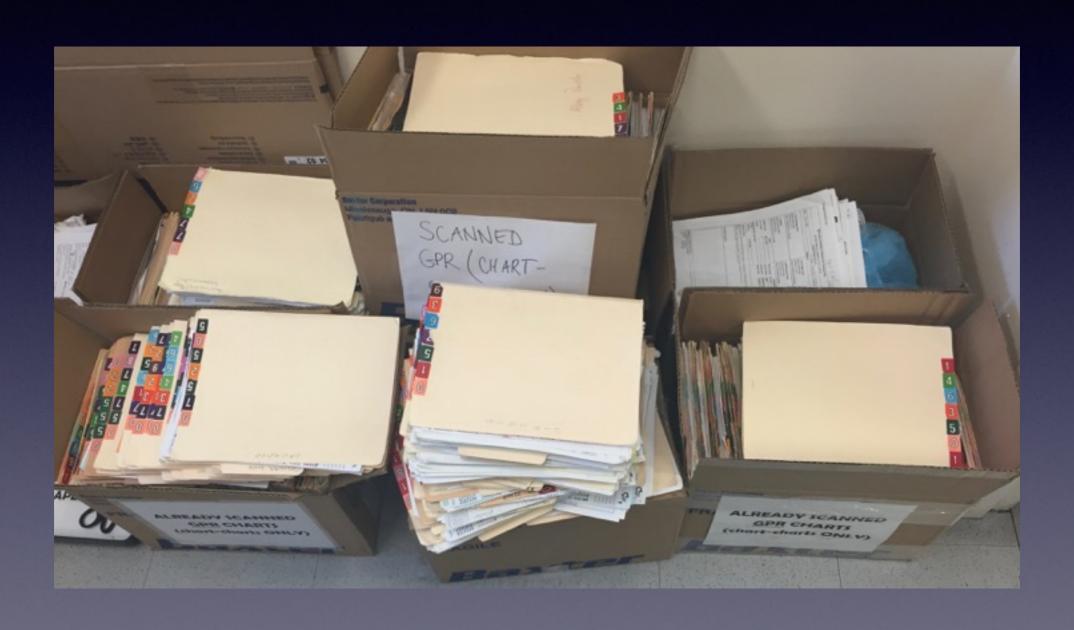
• Purpose:

 To create a standardized high quality hospital based cancer registry for all patients with oral and maxillofacial cancers treated in our department.

> Quality Assurance

Scientific Contribution

Data!!!!!





Data collection and Sorting

1. Data collection and Sorting

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High Quality Standardized Data 2. Standardized prospective and retrospective data entry

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Data Registry

3. Creation of a web-based (HTML) database to collect and store data

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Data Registry

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Data Analysis 4. Data entry, validation and statistical analysis

1. Tertiary Care Centre (Major referral Centre)

2. Out-Patient visits: >2000/year

New Patient Assessment: >250/year

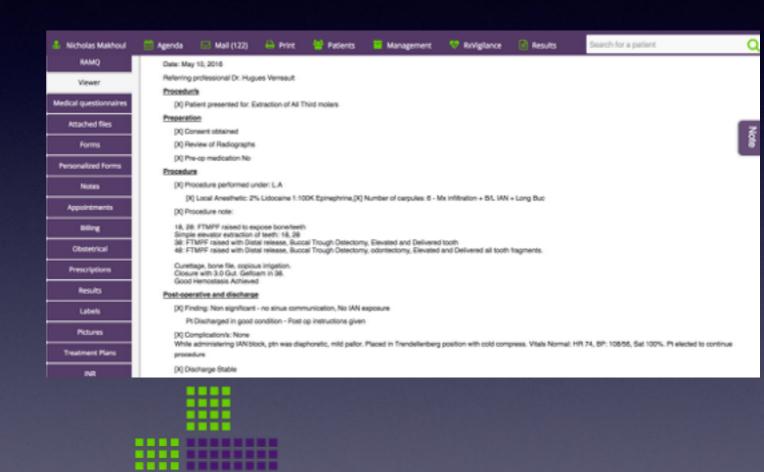
Patient Follow Ups: >1750/year

New Cancer Assessment: 50-70/year

Major Cancer Surgery: 40-60/year

Major Microvascular Surgery: 40-50/year







High Quality Standardized Data

TREATMENT	& CLINIC RECORD	STAMP PATIENT'S CARD				
	12.12					
	4,505.7,6					
		2351 2311				
		2017.04				
		370407 £				
DATE YYYY/MM/DD	COMPLETE TREATMENT DETAILS Include tooth number, area, anesthetic, medications, materials used, cavity depth, details encountered, & if treatments is completed or in progress Also please include the supervising DDS and resident name					
MAY 1 5 2015	TD 33					
	RFC: Flap Pailine.					
	HPS: DE was diagnosed with Cancer 6 years ago. Had sugger					
	resection & PCap. recurrence 4 times.					
	Lost suggy was Market 9th, 2015.					
	PMH:					
	Med:					
	All: & NKDA.					
	PST: 4 Surgeries resection.					
	icial & smoking , ETOH +					
	eren pamoping / Eren 4					

High Quality Standardized Data

MGH ORAL AND MAXILLO MAXILLOFACIAL ONCOLO		
Date:		natient's contact #
Age: Sex: □		
		Others:
Reason for Referral:		
Patient's complaint and Histor	• •	
Date of First time patient sought		Consult done by:
If patient notified about the diag		Consult done by:
Other pertinent history:		
outer pertinent motory.		
Loss of Appetite: ☐ No ☐ Ye Nausea/Vomiting: ☐ No ☐ Ye		of weight: □No □Yes reats: □No □Yes
Other symptoms: No You If yes, Pain Paresthe Other: Medical History: CVS:	esia Dyspnea D	Dysphasia
If yes, □ Pain □ Paresthe □ Other: Medical History: □ CVS:	esia Dyspnea D	D:
If yes, □ Pain □ Paresthe □ Other: Medical History: □ CVS: □ Respiratory:	esia	o:
If yes, □ Pain □ Paresthe □ Other : Medical History: □ CVS: □ □ Respiratory: □	esia	o:
If yes, Pain Paresthe Other: Medical History: CVS: Respiratory: Endocrinology:	esia	o:
If yes,	esia	o:
If yes,	Besia Dyspnea Gastro Neuro Other t Attached B-Blocker: N	o:
If yes,	Besia Dyspnea Gastro Neuro Other t Attached B-Blocker:	o:
If yes,	Besia Dyspnea Gastro Neuro Other t Attached B-Blocker: N	D:
If yes,	Besia Dyspnea Gastro Neuro Other t Attached B-Blocker: N	o:
If yes,	Besia Dyspnea Gastro Gastro Neuro Other t Attached B-Blocker: DN Yes: Ves: Number of years: Newror of quitting:	D:
If yes,	Gastre Ga	Discrete
If yes,	Gastre Ga	D:
If yes,	Gastre Ga	Discrete

Clinical Examination:	
General Appearance:	
Head:	
Neck:	
ntraoral (lips, tongue, FOM, pharynx, buccal/alveolar mucosa, de	ntition, saliva):
Flex scope: □Not Indicated □Done, findings:	
maging (including panoramic radiographs, periapical radiographs	, CT, MRI):
mpression (summary includes age, short description of the lesion	
Impression (summary includes age, short description of the lesion	n, problem):
impression (summary includes age, short description of the lesion	n, problem):
Impression (summary includes age, short description of the lesion Differential Diagnosis:	n, problem):
Impression (summary includes age, short description of the lesion Differential Diagnosis: Plan: Biopsy (incisonal, excisional, FNA):	n, problem):
Impression (summary includes age, short description of the lesion Differential Diagnosis: Plan: □Biopsy (incisonal, excisional, FNA):	n, problem):
Impression (summary includes age, short description of the lesion Differential Diagnosis: Plan: Biopsy (incisonal, excisional, FNA): Biopsy completed, diagnosis:	n, problem):
Impression (summary includes age, short description of the lesion Differential Diagnosis: Plan: □Biopsy (incisonal, excisional, FNA):	n, problem):
Impression (summary includes age, short description of the lesion Differential Diagnosis: Plan: Biopsy (incisonal, excisional, FNA): Biopsy completed, diagnosis: Imaging (specify):	n, problem):
mpression (summary includes age, short description of the lesion Differential Diagnosis: Plan: Biopsy (incisonal, excisional, FNA): Biopsy completed, diagnosis: Imaging (specify): Blood test (specify):	n, problem):

High Quality Standardized Data

1. Defining a minimum data set

- Investigate available data sets
- Consider the need for specific additions
 - Level 1: General Demographics
 - Level 2: General Health Items
 - Level 3: General Cancer Items
 - Level 4: Specific Cancer Items
 - Level 5: Follow up (Survival)

	Chirurgie Oncologique et				
	IGH ORAL AND MAXILLOFACIAL SURGERY IAXILLOFACIAL ONCOLOGY CONSULT FORM				
	patient's contact #				
	ge: Sex: \(\sum M \) \(\sup F \)				
R	teferral: General Dentist: OMFS: Others:				
R	Reason for Referral:				
P					
	ate symptoms started/Lesion noticed for first time:				
	tate of First time patient sought medical consultation:Consult done by:				
	If patient notified about the diagnosis, give date:				
O	Other pertinent history:				
-					
If	ther symptoms: No Yes: yes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other:				
If	Yes, ☐ Pain ☐ Paresthesia ☐ Dysphasia ☐ Difficulty chewing ☐ Other: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐				
If	Pain				
M	Syes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other: Medical History:				
M =	Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other: Gastro: Respiratory: Respiratory: Colorinology: Colo				
M C	Tyes,				
Iff	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other:				
M L A	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other:				
Iff M M M L A Si	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other:				
Iff M M M L A Si Si	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other :				
Iff M M M L A Si Si	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other :				
M L A So So	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other :				
M L A Si Si A	Tyes,				
Iff	Tyes, Pain Paresthesia Dyspnea Dysphasia Difficulty chewing Other :				
M L A A Si Si Si Si Si	Pain				

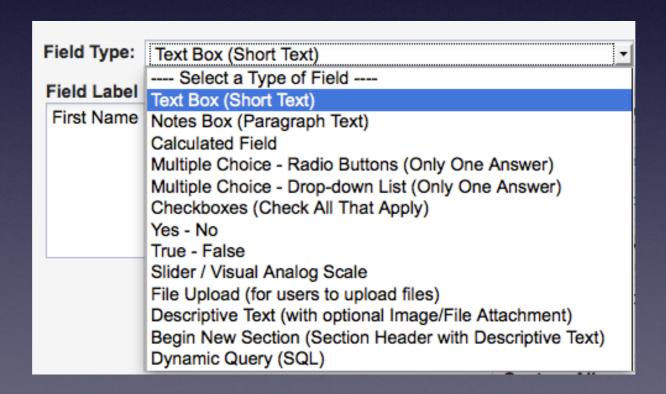


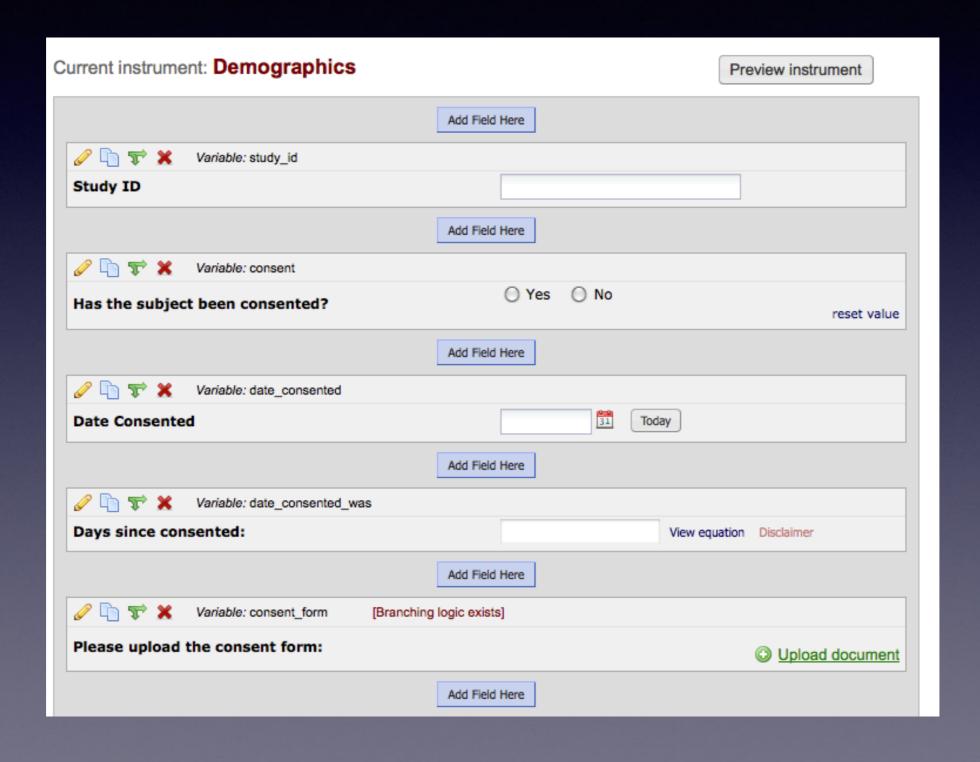
 REDCap (Research Electronic Data Capture) is a webbased application used to create forms and manage databases in order to support data capture and surveys for research studies.

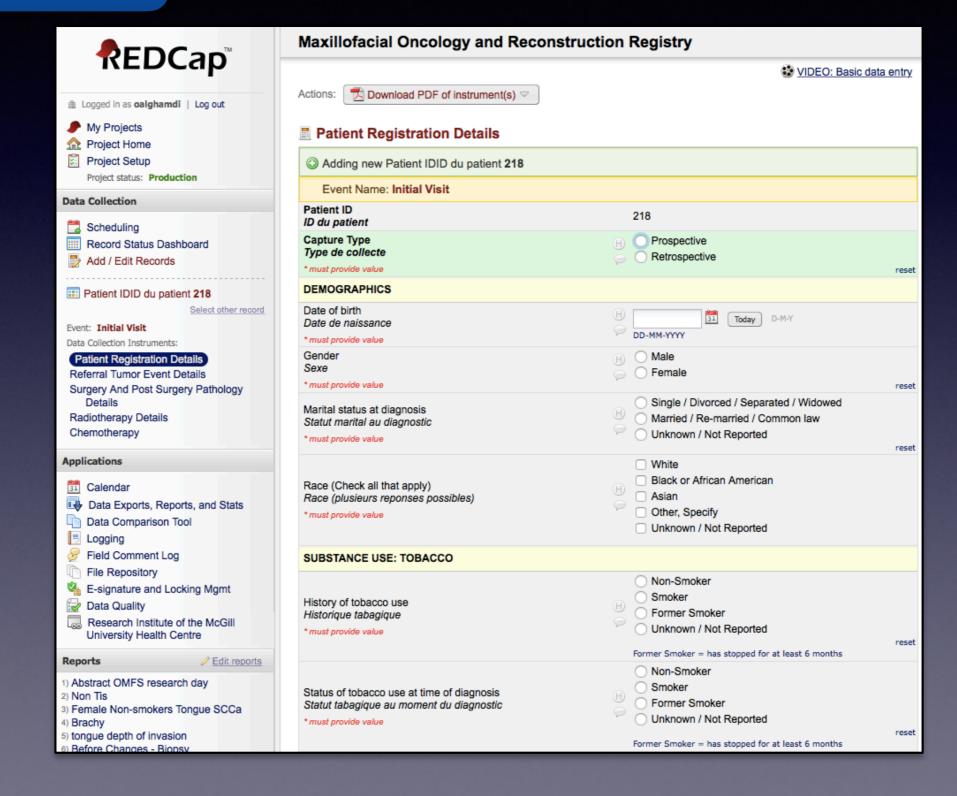


- Authenticated access
- Secure hosting, back ups and maintenance automatic
- Allows multi-site access (Multi-Centred Studies)
- Can share projects with other institutions
- Research teams can input data simultaneously, data can be collected at one site.
- Branching logic is supported

- Databases or surveys can be built rapidly
- Form creation and data entry are easy in the web interface







Longitudinal Prospective Oral Oncology Registry

Patient Intake

Patient consented Given Study ID Std. Intake Sheet Surgery

Operative Report Final Pathology

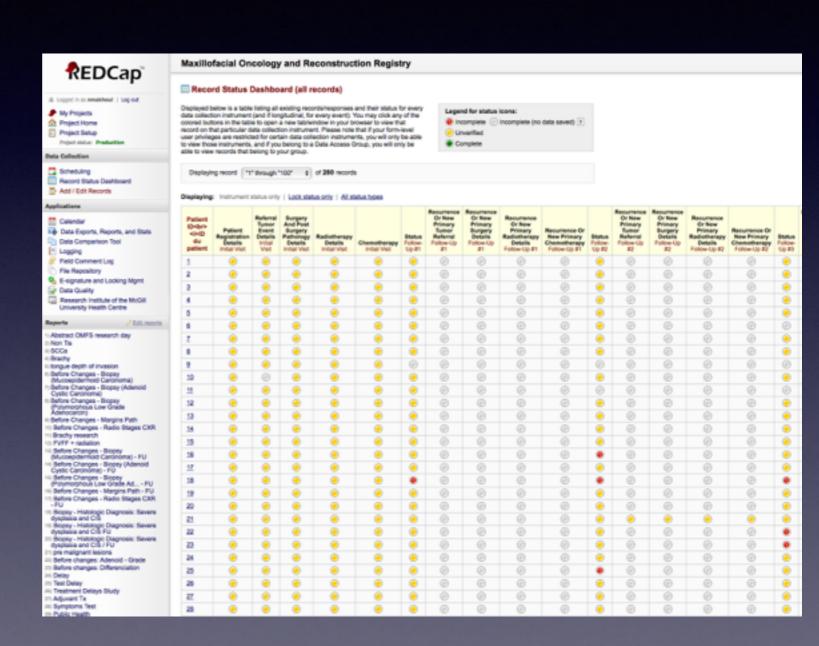
Adjunct Tx

Details on Chemo and/or Radiation

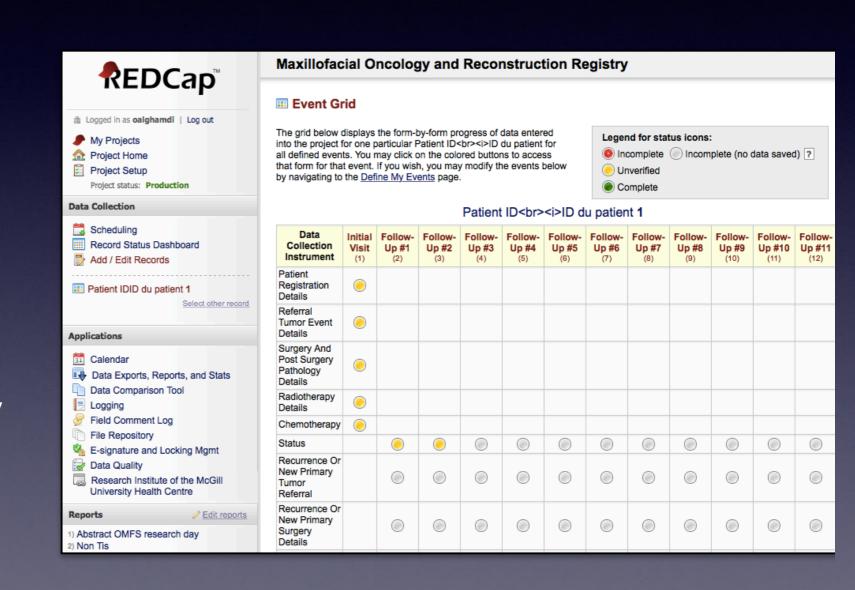
Follow Up

5 year Follow Up Data entered 2x/Year

- Data collection (2013)
- De-Identified Data Set
- Approximately 300 patients
- Each patent ~250 data points
- Follow up for up to 5 years

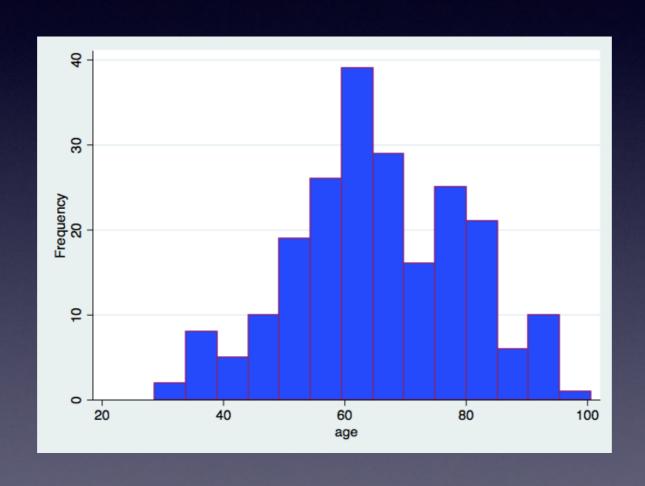


- Time 0
 - 5 data sheets
- Follow Up
 - One data sheet
- If recurrence or new primary
 - New full set of data



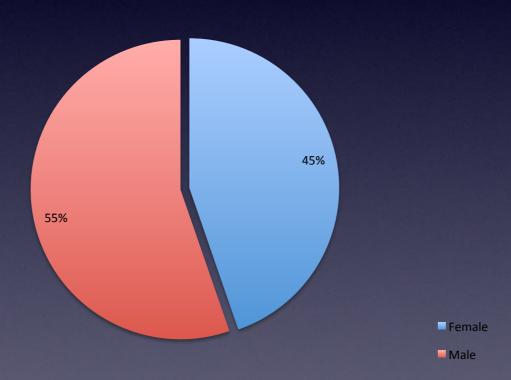
- Data Comparison Tool
 - Used to compare two records in a project
- Data Quality Tool
 - Missing Values
 - Validation Errors (incorrect or out of range)
 - Outliers
 - Hidden fields with values
 - Multiple choice fields with invalid data

- Double Data Entry
 - Two persons perform data entry
 - Assigned to different individuals
 - A reviewer reconciles differences
- Export data to a variety of statistical analysis packages
- Exports are customizable, including all or some of the data forms and fields



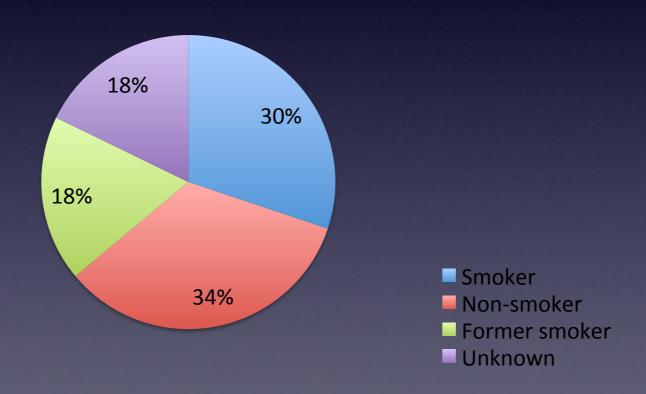


Gender



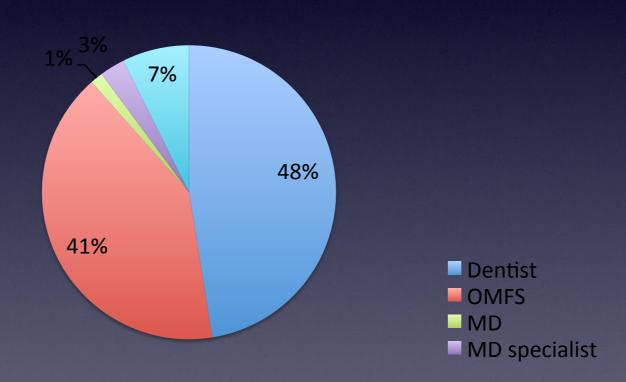


Smoking History

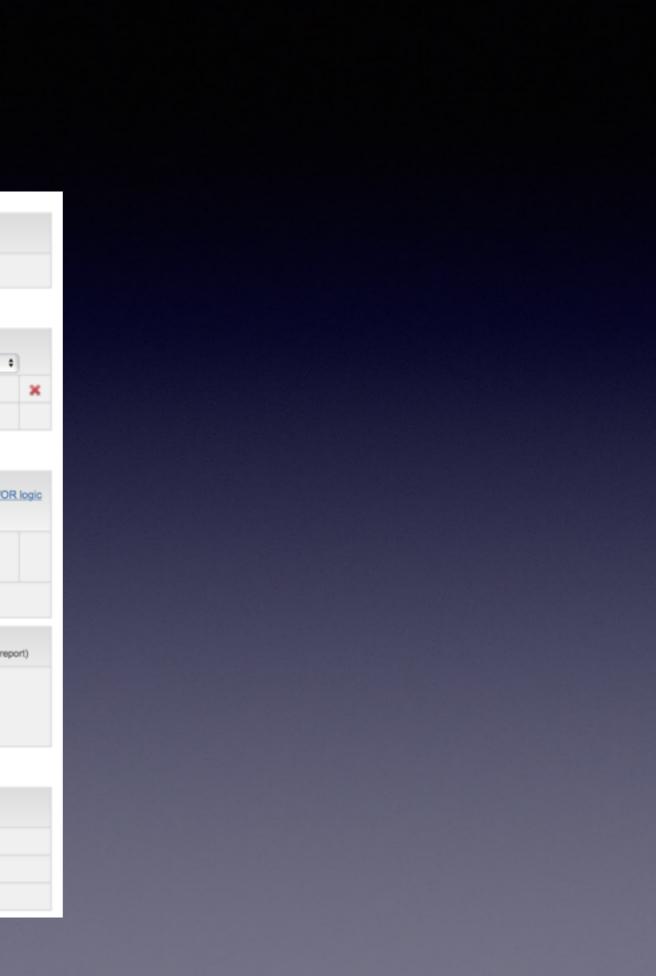


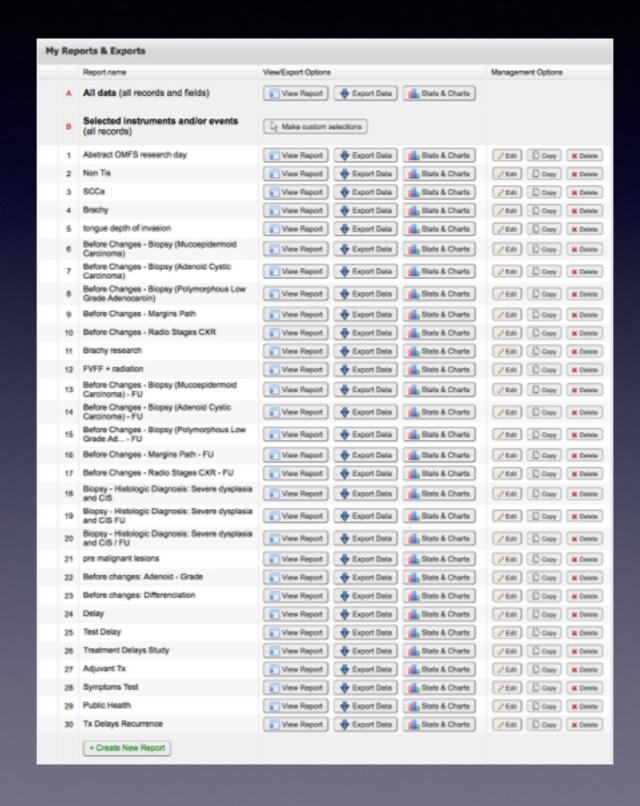


Referral



hoose who sees th	is report on their let	ft-hand	d project m	nenu [?	?		
- Custom use	raccess (Choose spe	ecific us	ers, roles, or	data acr	ccess groups who will have access)		
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	Add all fields f	rom sek	ected instrum	nent: -	choose instrument		
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Type variable name	or field label						
events for each re	cord returned ?				How to use filte	rs and AND/OR	logic
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	or field label			=	0		
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Follow-Up #1 Follow-Up #2 Follow-Up #3 Follow-Up #4							
Its (optional)							
studyid "Patient ID-	<i>ID du patient"</i>	•	DOC	Aso	cending order \$		
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Conclusion

- Ultimately:
 - Improve quality of care, quality control and quality assurance
 - Adding more centres to our database
 - Establishing randomized clinical trials

The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

Related article, p. 1587

- Observational registries
- High quality registries standardized data
- Identify possible causal links between treatment and outcomes
- Pointed and effective way to structure a trial

Thank you









