

Morbidity Adjudication and Tracking during DCCT/EDIC

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Background

- In a long term epidemiology study of type 1 diabetes, looking at cardiovascular disease adjudication is important.
- The collection and analysis of event data in diabetes clinical trials are time consuming and labor intensive. Even in the best of circumstances.
- The majority of events may be impossible to adjudicate, especially endpoints like angina, arrhythmia, and TIA.

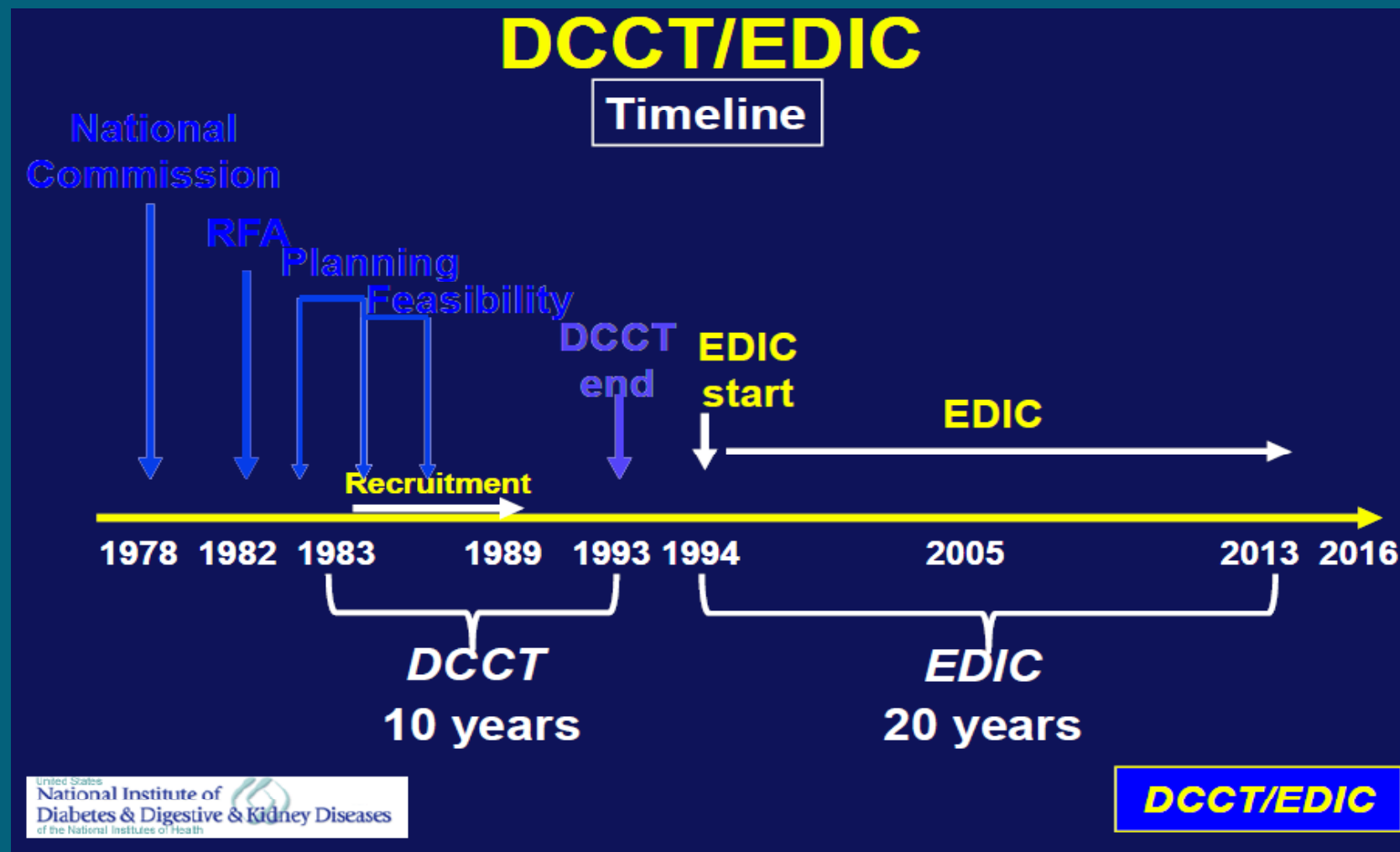
Objectives

- **To establish a surveillance and adjudication process to classify the major cardiovascular outcomes.**
- **To describe the expedition of adjudication time by this surveillance process.**

Methods

- **The Diabetes Control and Complications Trial (DCCT):**
 - **A multi-center clinical trial (1983-1993)**
- **The Epidemiology of Diabetes Interventions and Complications (EDIC) (1994 - 2017):**
 - **The observational follow up of the Diabetes control and Complications Trial (DCCT) cohort**

Methods



Methods

Study Cohort – Age 13-39

- **Primary prevention:**
1-5 years duration
No retinopathy or microalbuminuria
- **Secondary intervention:**
1-15 years duration
 ≥ 1 microaneurysm, < severe NPDR
< 40 mg albumin excretion/24 h

Methods

Data Collection

- Annual Form
- Verification Forms
- Medical Records

Methods

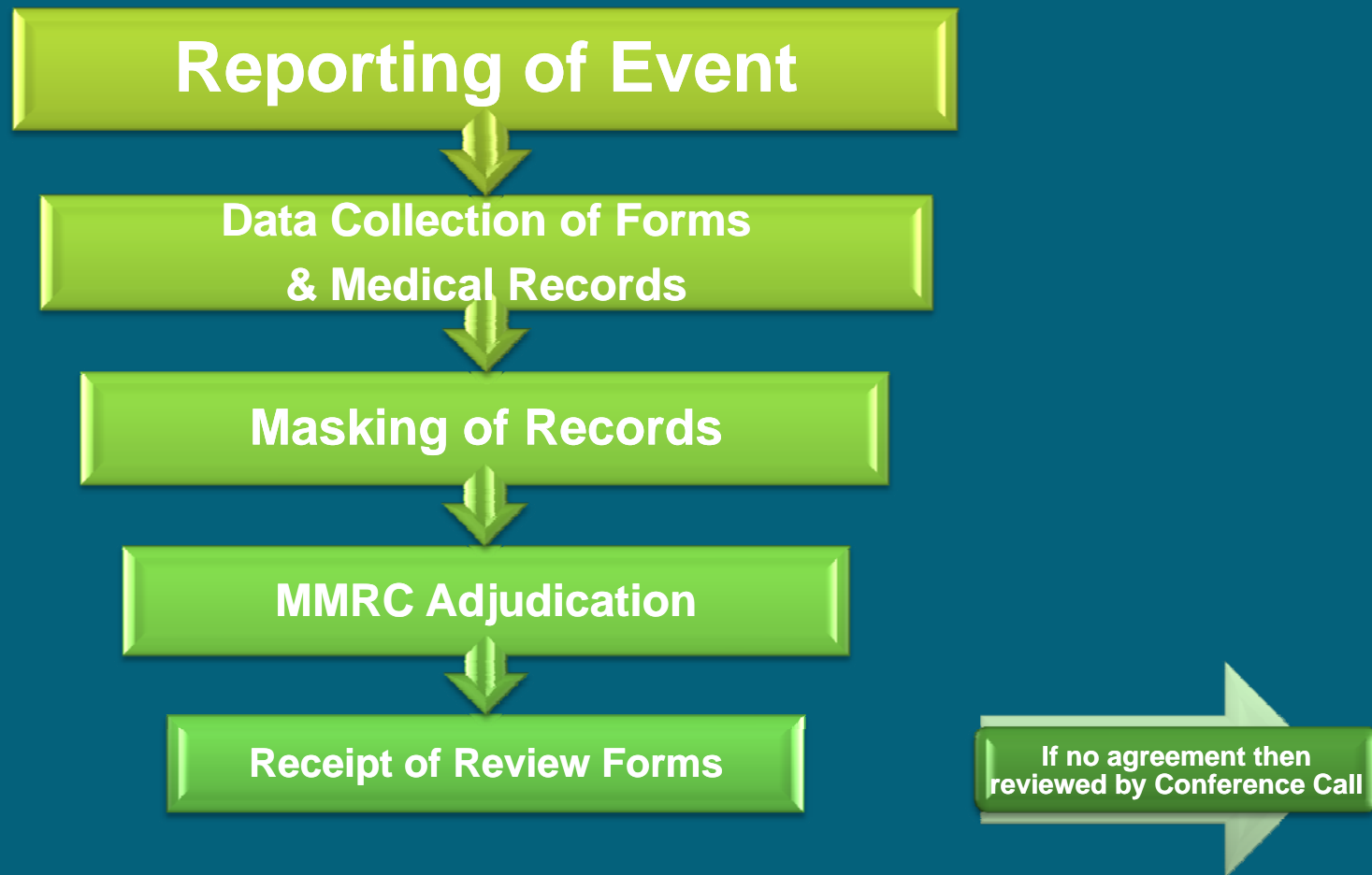
- Events are categorized into seven types of verification events in EDIC:
 - 1) Cardiovascular Disease
 - 2) Cerebrovascular Event
 - 3) Peripheral Vascular Event
 - 4) DKA Event
 - 5) Psychiatric Disease Requiring Treatment
 - 6) Major Accident
 - 7) Renal Failure Event (Dialysis of Kidney Transplant)

Methods

- **Reported CVD events are categorized into seven types of adjudicated events in EDIC:**
 - 1) Myocardial Infarction**
 - 2) Revascularization**
 - 3) Congestive Heart Failure**
 - 4) Stroke**
 - 5) Angina**
 - 6) Arrhythmia**
 - 7) Transient Ischemic Attack**

Adjudication Process

Five-step Adjudication Process



Completeness of Follow-up

	DCCT		EDIC		
	<u>Baseline</u>	<u>Study End</u> (1993)	<u>Baseline</u> (1994)	<u>Year 11</u> (2005)	<u>Year 18</u> (2012)
Number	1441	1430	1428	1392	1341
Percent of Surviving Cohort	100	99	99	96	93

DCCT/EDIC

Results

Table 1. Final Status of Reported Event during EDIC Year 1 – 18

	N	%
Overall	670	100
Lack of Documentation	261	39.0
Adjudicated Event	409	61.0
Reviewed as an Event	280	41.8
Reviewed as not an Event	125	18.7
Undecided	4	0.6

Figure 1.

Percent of reported events that were adjudicated as the actual event



**Table 1A. Final Status of Reported Event during EDIC Year 1 – 18
by year**

	< 2009			≥ 2009	
	N	%		N	%
Overall	547	100		123	100
Lack of Documentation	233	42.6		28	22.8
Adjudicated Event	314	57.4		95	77.2
Reviewed as an Event	210	38.4		70	56.9
Reviewed as not an Event	101	18.5		24	19.5
Undecided	3	0.6		1	0.8

Figure 2. Percent of reported events that were adjudicated as the actual event by clinic

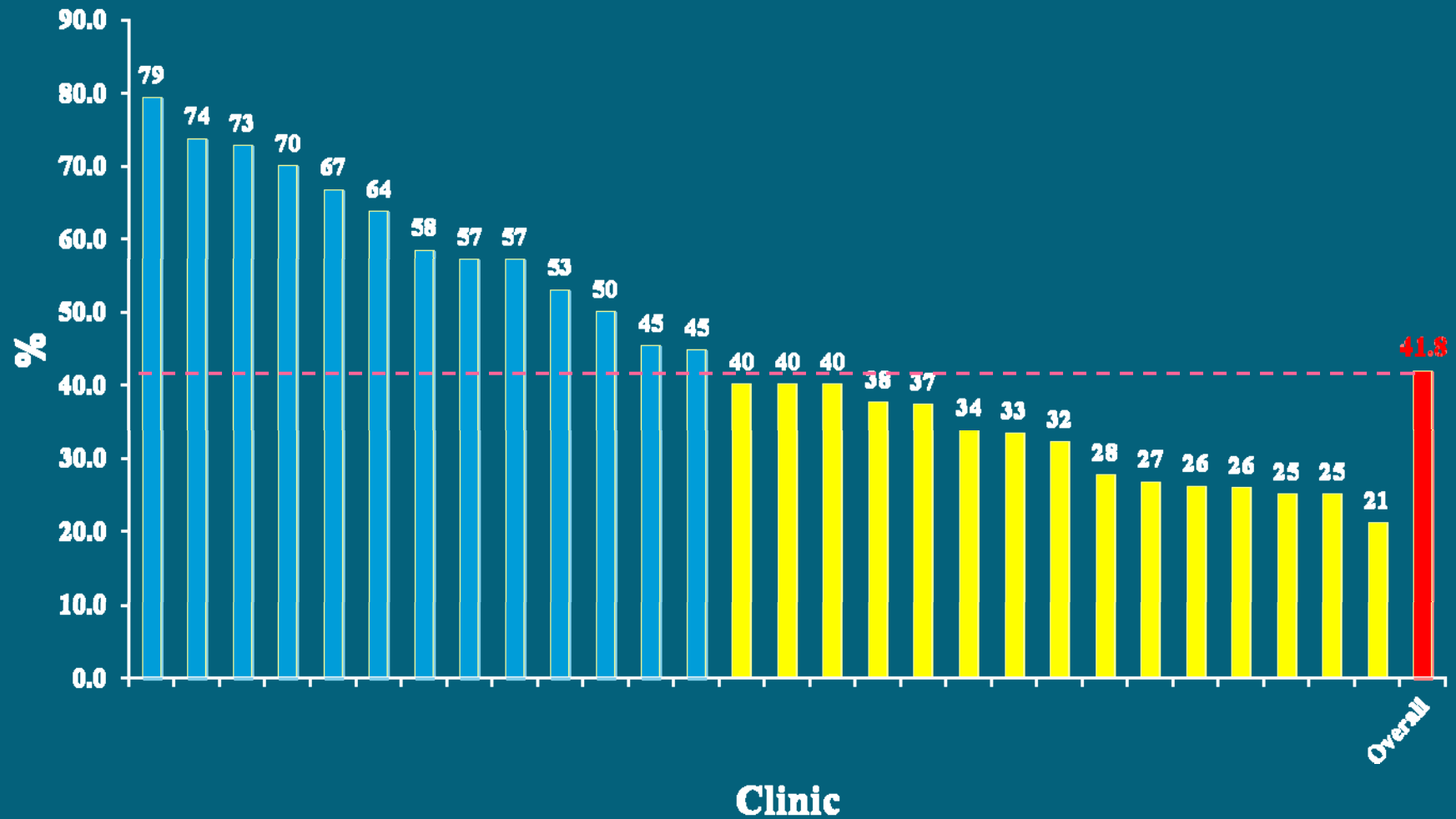


Figure 2A. Percent of reported events that were adjudicated as ANG/ARR event by clinic

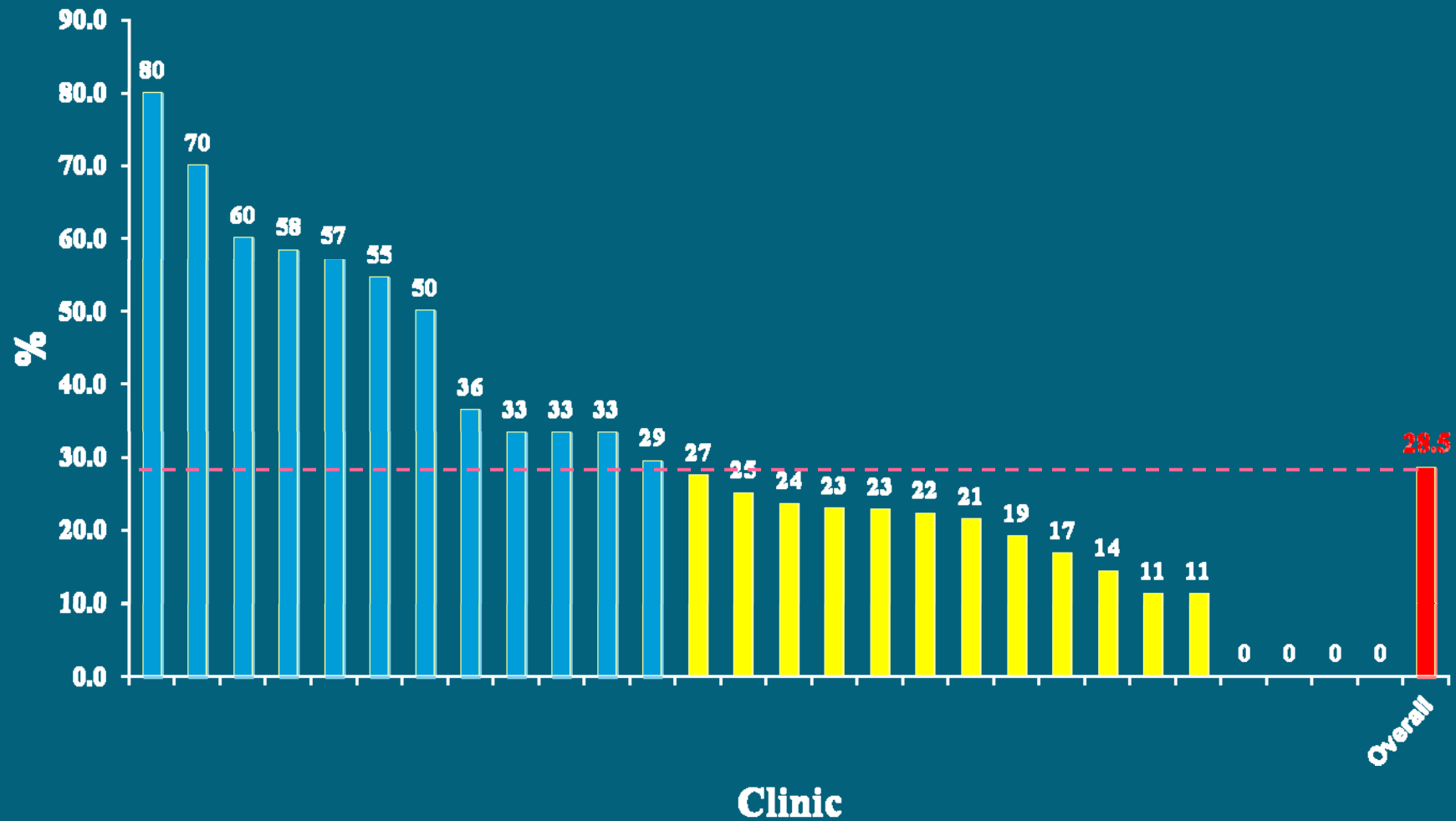


Figure 2B. Percent of reported events that were adjudicated as CAD event by clinic

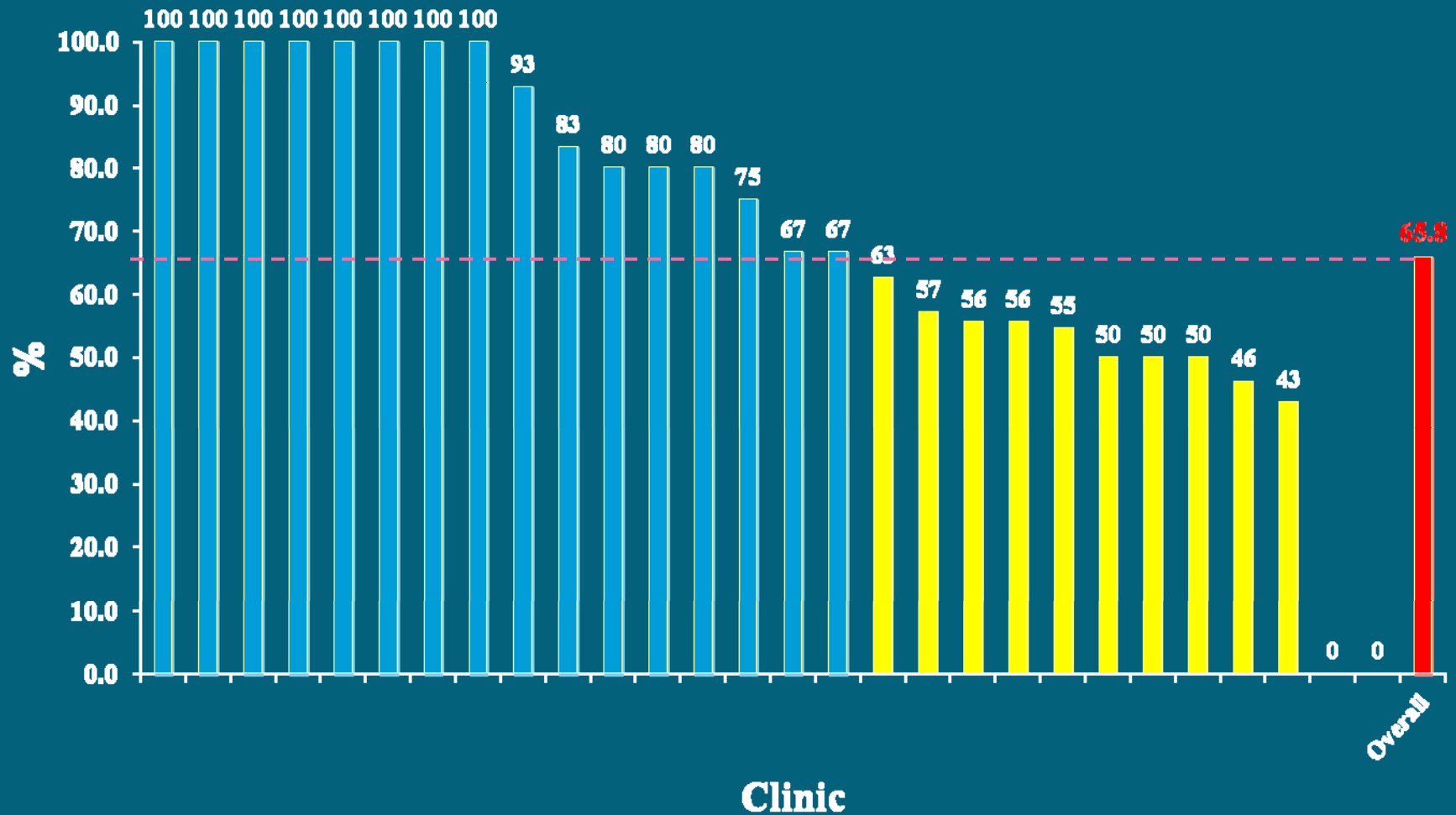


Figure 2C. Percent of reported events that were adjudicated as CHF/CVA/TIA event by clinic

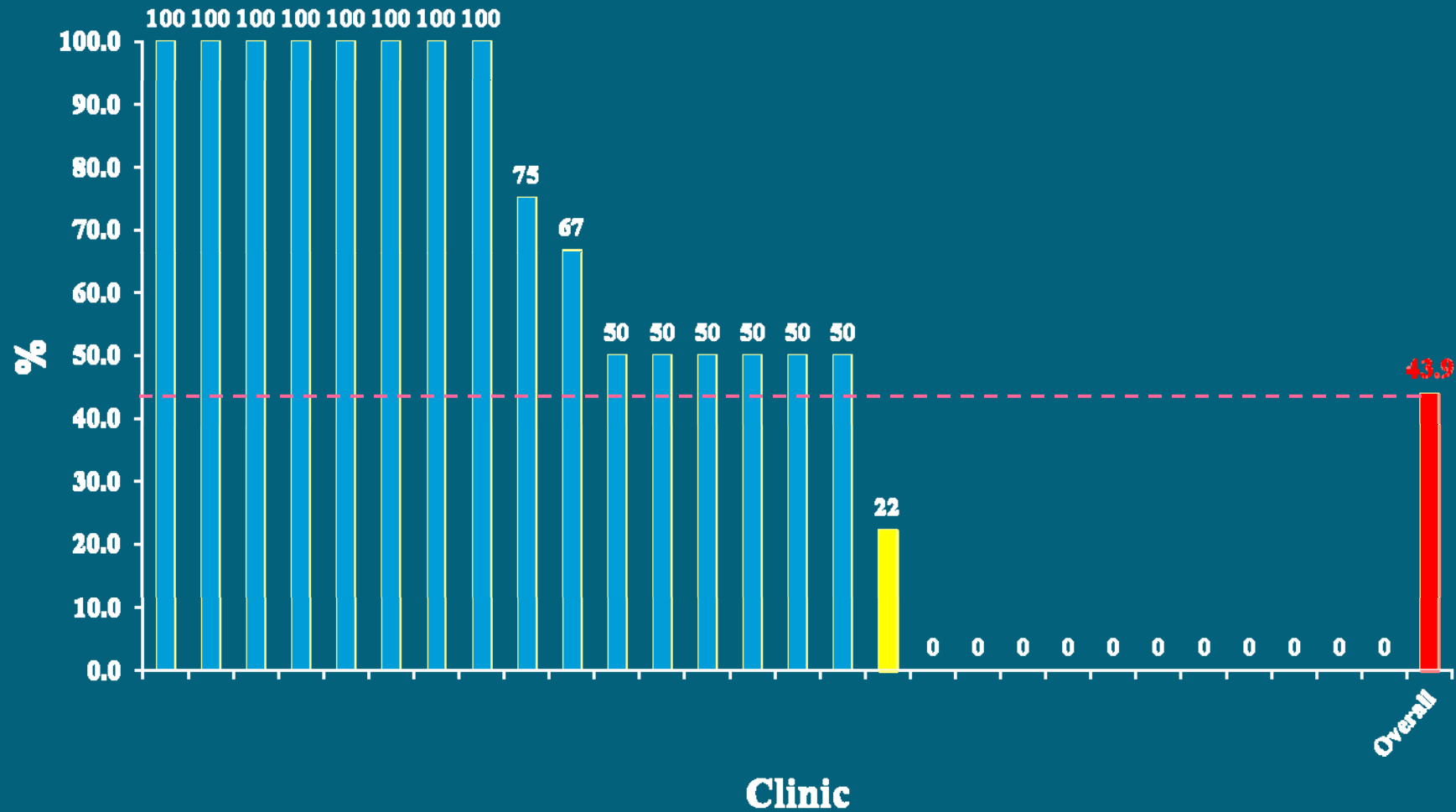


Figure 2D. Percent of reported events that were adjudicated as MI event by clinic

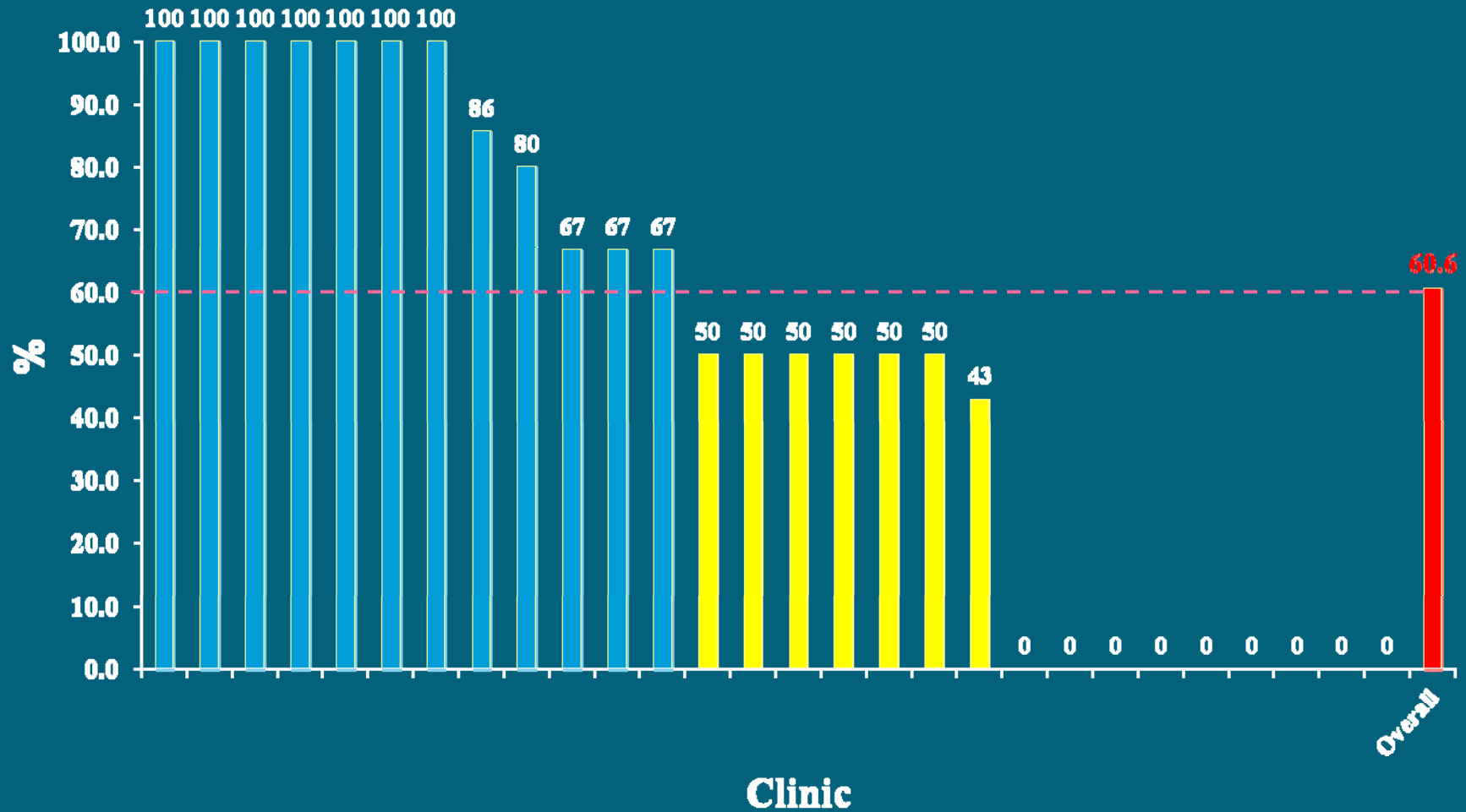


Table 2A. Time between Event Reported and Records Requested

	N	Mean ± SD (days)
Time between event reported and records requested	465	115 ± 213

Table 2B. Time between Records Requested and Records Received

	N	%	Mean ± SD (days)
Time between records requested and records received	379	100	125 ± 304
without requesting records	119	31	0
with requesting records	260	69	182 ± 353

Figure 3. Time between Records Requested and Records Received by Clinic



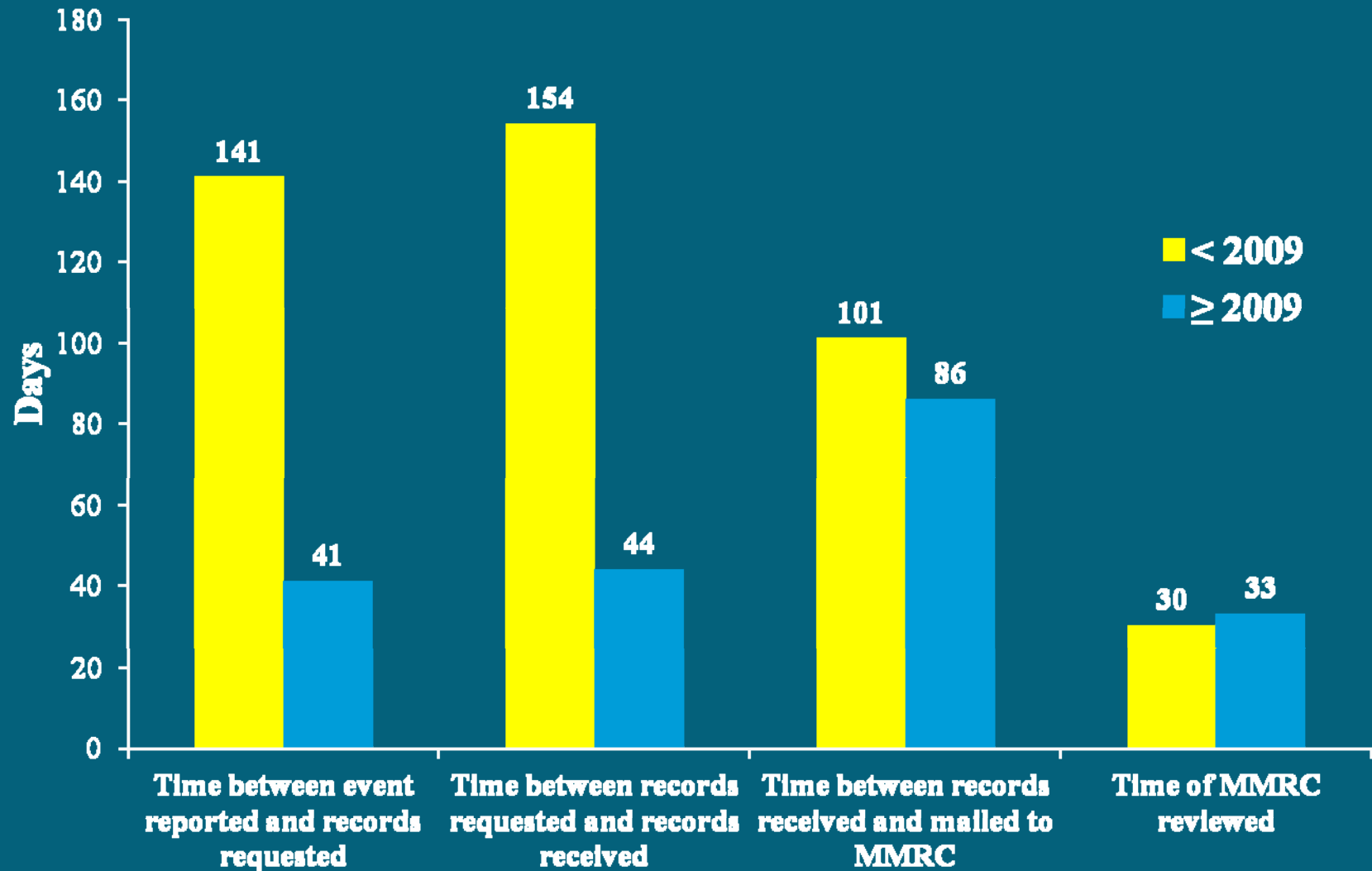
Table 2C. Time between Records Received and MMRC Reviews

	N	Mean ± SD (days)
Time between records received and mailed to MMRC	354	97 ± 128
Time of MMRC reviews	354	31 ± 11

Table 3. Time Required to Complete Data Collection by year

	< 2009		≥ 2009	
	N	Mean ± SD	N	Mean ± SD
Time between event reported and records requested	343	141 ± 241	122	41 ± 46
Time between records requested and records received	278	154 ± 347	101	44 ± 85
Time between records received and mailed to MMRC	258	101 ± 137	96	86 ± 100
Time of MMRC reviews	258	30 ± 13	96	33 ± 7
Total	258	389 ± 413	96	199 ± 128

Figure 4. Time Required to Complete Data Collection by year



Conclusion

Time it took to adjudicate events before 2009 in EDIC

- **389 ± 413 days**

Time it takes to adjudicate events after 2009 in EDIC

- **199 ± 128 days**

Adjudication time has been reduced by half over the past five years.

Discussion

- Events are “self-reported”.
- Some events have more consistent documentation than others.
- The coronary artery disease (CAD) outcome is clearly defined, and there is good adherence in collecting sufficient documentation.
- For 21% of events, records were not obtained because the patient, hospital, or health care provider were not willing to provide medical records.