

Prospective Activity: AE Review Form – client VMMC follow-up review

Site name _____ Date _____ Site type: Outreach Mobile Static

Reviewer _____ Dates of in-person reviews observed _____ Cadre of person observed: nurse doctor

VMMC follow-up reviews	Client order																								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Client review characteristics																									
Review Day	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	2 7 14	
AE identified by site staff	Y N																								
Actual AE present	Y N																								
AE type identified correctly	Y N																								
AE severity identified correctly	Y N																								
AE reviewed with staff	Y N																								

TOTAL NUMBER OF AEs IDENTIFIED BY SITE STAFF: _____ TOTAL NUMBER OF AEs IDENTIFIED BY ZAZIC STAFF _____

Notes _____

Site team QA representative signature _____

Retrospective AE Review Form – Register Data Review - July-December 2016

Site name _____ Date _____ Site type: Outreach Mobile Static

Reviewer _____ Month(s) of reviewed data _____ Register pages reviewed: _____

Site team QA representative signature _____

VMMC procedure characteristics	VMMC register PAGE reviewed (check if complete. Leave BLANK if incomplete or incorrect)																								
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
VMMC Register																									
Adverse event section complete - Day of Procedure (severity + code)																									
1 st post-procedure review AE section complete (Day 2 or Day 7) (severity + code)																									
2 nd post-procedure review AE section complete (Day 7 or Day 14) (severity + code)																									
3 rd post-procedure review AE section complete (Day 42 or Day 49) (severity + code)																									
Additional post-procedure review AE section complete (if applicable) (severity + code)																									
Comments completed – if applicable																									

IN THE PAST 3 MONTHS:

TOTAL NUMBER OF AEs IDENTIFIED FROM DATA: _____ TOTAL NUMBER OF AEs REPORTED ON MRF TO PARTNER: _____ TOTAL NUMBER OF AEs IN DHIS2: _____ : _____

Notes _____

Retrospective AE Review Form – CIF Data Review - July-December 2016

Site name _____ Date _____ Site type: Outreach Mobile Static

Reviewer _____ Month(s) of reviewed data _____ **CIF file numbers reviewed:** _____

Site team QA representative signature _____

VMC procedure characteristics	CIF reviewed (check if complete. Leave BLANK if incomplete or incorrect)																									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
CIF																										
Adverse event section complete - Day of Procedure (severity + code)																										
1 st post-procedure review AE section complete (Day 2 or Day 7) (severity + code)																										
2 nd post-procedure review AE section complete (Day 7 or Day 14) (severity + code)																										
3 rd post-procedure review AE section complete (Day 42 or Day 49) (severity + code)																										
Additional post-procedure review AE section complete (if applicable) (severity + code)																										
Comments completed – if applicable																										

IN THE PAST 3 MONTHS:

TOTAL NUMBER OF AEs IDENTIFIED FROM DATA: _____ TOTAL NUMBER OF AEs REPORTED ON MRF TO PARTNER: _____ TOTAL NUMBER OF AEs IN DHIS2: _____

Notes _____

Retrospective AE Review Form – AE Log Review - July-December 2016

Site name _____ Date _____ Site type: Outreach Mobile Static

Reviewer _____ Month(s) of AE Log reviewed: _____

Site team QA representative signature _____

VMNC procedure characteristics	AE Log Month reviewed (check if complete. Leave BLANK if incomplete or incorrect)																									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
1. AE Log																										
Any AE reported?																										
If yes, take photo of each report/line with client name/number covered																										

IN THE PAST 3 MONTHS:

TOTAL NUMBER OF AEs IDENTIFIED FROM DATA: _____ TOTAL NUMBER OF AEs REPORTED ON MFR TO PARTNER: _____ TOTAL NUMBER OF AEs IN DHIS2: _____

Notes _____

Details on AE on-site management

1. Who does AE documentation at your site?
2. What forms do you use to document AEs?
3. How do you report AEs at your facility and what are the reporting timelines?
4. Do you have challenges in reporting AEs?
5. Who reports/compiles/completes AEs on the MRFs?
6. Do you think the team has been picking up and reporting AEs. If not what may be the causes
7. Does your site face challenges in doing reviews? Probe for transport, Staffing and AE review schedule challenges
8. Can you describe your facility's AE review system?