New Data Collection Form Data Items Data Dictionary

Version: 1.0

1 April 2023

Contents

Introduction

The Australian Breast Device Registry data dictionary defines each field of data according to the Data Collection Form (v2_20220217). It provides information on how the required data is sourced and entered into the database. The dictionary itself is presented with a contents page and then each field of data according to where it is presented in the Data Collection Form. Please be advised that an asterisk (*) indicates a new data field that has been included as an addition to the original data collection form.

Data Item Specifications and Abbreviations

Section of DCF	The title of the sections of the ABDR data collection form
Data Element Name	A Name to be used by the Researchers to describe this Data Element
Definition	A concise statement that expresses the essential nature of a Data Element and its differentiation from all other Data Element
Purpose	This is the purpose or reason assigned by the Researchers to collect this Data Element
Data Collection Requirement	This indicates if Data is requested, whether it is (I) mandatory; (ii) it is optional
Data collection	Describes whether the (I) collection is required or it is (ii) derived or calculated field or (iii) system generated field
Definition source	It indicates the source of definition of each data element: e.g., Meteor, ICOBRA MDS Consensus study

Abbreviations:	
BDR	Breast Device Registry
PROMs	Patient Reported Outcome Measures
ICOBRA	International Collaboration of Breast Registry Activities
MDS	Minimum Data Set
IV	Intravenous
IM	Intramuscular

1. Patient Details

1.1 Patient UR

Definition:	The Unit Record number allocated to a patient that can be used as a unique identifier across a range of systems at or within the operative institution
Purpose:	Patient identification (hospital specific)
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.2 First Name

Definition:	The person's identifying name within the family group or by which the person is socially identified
Purpose:	Patient identification, patient letters and PROMs
Data Requirement:	Mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.3 Middle Name

Definition:	A person may have more than one Given name or a "middle name". The second given name follows the given name recorded and is not the family name
Purpose:	Patient identification, patient letters and PROMs
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.4 Family Name

Definition:	The part of a name a person usually has in common with some other members of his/her family, as distinguished from his/her given names, as represented by text
Purpose:	Patient identification, patient letters and PROMs
Data Requirement:	Mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.5 Birth Date (dd/mm/yyyy)

Definition:	The date of birth of the person
Purpose:	Patient identification, calculation of age at date of operation
Data Requirement:	Mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.6 Medicare Number

Definition:	Person identifier, allocated by the Health Insurance Commission to eligible persons under the Medicare scheme, that appears on a Medicare card
Purpose:	Patient identification
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.7 Address

Definition:	Expressed as Street number, Street or Road name, Suburb Street number :An alphanumeric identifier, forming part of an address, used to identify the channel of postal delivery. Street or road name: The name of the road or thoroughfare applicable to the address site or complex, as represented by text. Suburb: The name of the locality/suburb of the address, as represented by text
Purpose:	Patient letters and PROMs
Data Requirement:	At least collection of one of these communication methods(address, mobile/landline, email) is mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.8 Post Code

Definition:	The Australian numeric descriptor for a postal delivery area for an address
Purpose:	Patient letters and PROMs
Data Requirement:	Collection is mandatory when address is selected as communication method
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.9 State

Definition:	An identifier of the state or territory of an address
Purpose:	Patient letters and PROMs
Data Requirement:	Collection is mandatory when address is selected as communication method
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.10 Mobile

Definition:	The patient's contact mobile number
Purpose:	Patient letters and PROMs
Data Requirement:	At least collection of one of these communication methods(address, mobile/landline, email) is mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.11 Landline

Definition:	The patient's contact home telephone number
Purpose:	Patient letters and PROMs
Data Requirement:	At least collection of one of these communication methods(address, mobile/landline, email) is mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.12 Email

Definition:	The patient's contact Email Address
Purpose:	Patient letters and PROMs
Data Requirement:	At least collection of one of these communication methods(address, mobile/landline, email) is mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.13 Gender: (F/M/Other)

Definition:	The distinction between male, female, and other genders which are a combination of male and female, or neither male nor female
Purpose:	Assists with determining reason for procedure
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	METEOR-635994

1.14 Height(cms)*

Definition:	The height of a person measured in centimetres
Purpose:	Used in the calculation of body mass index (BMI)
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	METEOR-270361

1.15 Weight(Kgs)*

Definition:	A measurement of body mass
Purpose:	Used in the calculation of body mass index (BMI)
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	METEOR-269197

1.16 Tobacco use within the last month (Yes/ No)*

Definition:	A person's smoking behaviour within the last month
Purpose:	To determine health outcomes and complication rates between patients who smoke and those who do not
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

1.17 Cosmetic Tourism (yes/no)

Definition:	Patient comes to Australia for cosmetic surgery
Purpose:	Assists with tracking devices implanted in Australia
Data Requirement:	Optional
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

2.Hospital and Surgeon Details

2.1 Operation Date (dd/mm/yyyy)

Definition:	The date on which a procedure commenced during an inpatient episode of care
Purpose:	Verification of surgical procedure, patient identification, case ascertainment and reporting
Data Requirement:	Mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

2.2 Hospital Name

Definition:	Hospital/ Site where the operation was performed
Purpose:	Verification of surgical procedure, patient identification and reporting
Data Requirement:	Mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

2.3 Surgeon Name

Definition:	Surgeon performing the operation
Purpose:	Verification of surgical procedure, patient identification and reporting
Data Requirement:	Mandatory
Data Collection:	collection is required
Definition Source:	BDR Data Dictionary

3. Device Details

3.1 Reference Number

Definition:	Catalogue reference number of the implanted device
Purpose:	Device identification- manufacturer
Data Requirement:	Mandatory
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.2 UDI*

Definition:	Unique Device Identification
Purpose:	Device identification- specific device
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-hub

3.3 Manufacturer

Definition:	Name of the manufacturer of the implanted device
Purpose:	Device identification- manufacturer
Data Requirement:	Mandatory
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.4 Lot

Definition:	Lot number of the implanted device
Purpose:	Device identification
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.5 Serial Number

Definition:	Serial number of the implanted device
Purpose:	Device identification- specific device
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.6 Shell

Definition:	The surface texture of the device being inserted
Purpose:	Identify device characteristics, potentially assists in tracking performance outcomes
Data Requirement:	Mandatory
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.7 Fill

Definition:	The material used to fill the breast implant: saline solution, silicone gel, or other
Purpose:	Identify device characteristics, potentially assists in tracking performance outcomes
Data Requirement:	Mandatory
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.8 Shape

Definition:	The shape of the device being inserted into the breast; where the shape of the device is either Round: implant is shaped like a flattened sphere or Shaped: a contoured shape that re-creates the more teardrop outline of a mature breast
Purpose:	Identify device characteristics, potentially assists in tracking performance outcomes
Data Requirement:	Mandatory
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

3.9 Volume of Implant(mls)

Definition:	As determined by the manufacturer or measured intraoperatively by weight, or displacement, or fill volume
Purpose:	Device characteristics, assists with (revision) procedure planning
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only, reposition and replacement with an autologous flap procedures
Definition Source:	ICOBRA MDS Consensus study

4.ADM / MESH Details

4.1 ADM/Mesh Product Name*

Definition:	Name of the ADM/Mesh- indicating product type
Purpose:	Device identification- Product Type
Data Requirement:	Optional
Data Collection:	Collection is required when ADM/Mesh used
Definition Source:	BDR Data Dictionary

4.2 ADM/Mesh Manufacturer

Definition:	Name of the manufacturer of the ADM/Mesh
Purpose:	Device identification- Manufacturer
Data Requirement:	Mandatory
Data Collection:	Collection is required when ADM/Mesh used
Definition Source:	ICOBRA MDS Consensus study

4.3 ADM/Mesh Reference Number

Definition:	Catalogue reference number of the ADM/Mesh
Purpose:	Device identification- Manufacturer
Data Requirement:	Mandatory
Data Collection:	Collection is required when ADM/Mesh used
Definition Source:	ICOBRA MDS Consensus study

4.4 ADM/Mesh Serial Number

Definition:	Serial number of the ADM/Mesh
Purpose:	Device identification- Specific device
Data Requirement:	Optional
Data Collection:	Collection is required when ADM/Mesh used
Definition Source:	ICOBRA MDS Consensus study

4.5 ADM/Mesh Lot

Definition:	Lot number of the ADM/Mesh
Purpose:	Device identification
Data Requirement:	Optional
Data Collection:	Collection is required when ADM/Mesh used
Definition Source:	ICOBRA MDS Consensus study

4.6 ADM/Mesh UDI*

Definition:	Unique Device Identification
Purpose:	Device identification- specific device
Data Requirement:	Optional
Data Collection:	Collection is required when ADM/Mesh used
Definition Source:	https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-hub

5.OPERATION DETAILS

5.1 Indication for Surgery

5.1.1 Cosmetic Augmentation

Definition:	A cosmetic procedure for enlarging breasts
Purpose:	To identify principal reasoning for the patient's operation for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the Indication of surgeries is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.1.2 Reconstruction: post mastectomy for cancer

Definition:	Surgical procedures performed to recreate a breast after one or both breasts are removed as a treatment for breast cancer
Purpose:	To identify principal reasoning for the patient's operation for data analysis and reporting purposes that may guide future best clinical practice.
Data Requirement:	Collection of one of the Indication of surgeries is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.1.3 Reconstruction: post risk reducing mastectomy*

Definition:	Surgery to remove one or both breasts to reduce the risk of developing breast cancer
Purpose:	To identify principal reasoning for the patient's operation for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the Indication of surgeries is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.1.4 Reconstruction: benign (developmental, gender reassignment or other)

Definition:	Surgery to restore or create shape and symmetry in patients with loss or absence of all or some breast tissue due to benign breast conditions, congenital deformity, tuberous breasts, or gender reassignment surgery
Purpose:	To identify principal reasoning for the patient's operation for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the Indication of surgeries is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2 Device Operation Type

5.2.1 First Implant Insertion

Definition:	An initial insertion of a new device, i.e. an implant or expander
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.2 Tissue Expander - Insertion

Definition:	An initial insertion of a new device, i.e. an implant or expander
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.3 Tissue Expander - Removal and Implant Insertion

Definition:	Removal of an expander and insertion of an implant (Secondary)
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.4 Implant - Replacement

Definition:	Revision of an in situ device, e.g. an implant or an expander revision
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.5 Implant - Explant Only

Definition:	Removal of an implant
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.6 Implant - Reposition

Definition:	Revision of an in situ device, e.g. an implant or an expander revision
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.7 Implant - Implant Removal and Tissue expander Insertion

Definition:	Revision of an in situ device, e.g. an implant or an expander revision
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.8 Tissue Expander - Replacement

Definition:	Replacement of a device with another tissue expander
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.9 Tissue Expander - Replacement with autologous flap*

Definition:	Replacement of Tissue Expander with patient's own tissue
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	At least collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.10 Tissue Expander - Explant Only

Definition:	Removal of an Expander
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.2.11 Tissue Expander - Reposition

Definition:	Repositioning of existing tissue expander
Purpose:	To specify the type of operation as it relates to the device being used and provides information regarding the patient surgical journey; e.g. primary or revision surgery
Data Requirement:	Collection of one of the Device Operation Types is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.3 Timing of Reconstruction

5.3.1 Immediate

Definition:	Breast reconstruction carried out at the time of mastectomy
Purpose:	To identify differences in the health outcomes of patients undergoing differing timed reconstructive procedures following mastectomy
Data Requirement:	Collection of one of the Timing of Reconstructions is Mandatory when indication of surgery is reconstruction
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.3.2 Delayed

Definition:	Breast reconstruction carried out at later time of mastectomy
Purpose:	To identify differences in the health outcomes of patients undergoing differing timed reconstructive procedures following mastectomy
Data Requirement:	Collection of one of the Timing of Reconstructions is Mandatory when indication of surgery is reconstruction
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

5.4 Previous Radiotherapy

Definition:	Radiotherapy to the breast or chest wall at any time prior to the current device operation
Purpose:	To determine health outcomes between patients who had previous radiotherapy and those who did not
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.ELEMENTS OF OPERATION

6.1 Incision Site

6.1.1 Peri areolar*

Definition:	An incision around the areola
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical incision locations
Data Requirement:	At least collection of one of the Incision Sites is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.1.2 Infra-mammary

Definition:	An incision in, or beneath the infra-mammary fold
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical incision locations
Data Requirement:	At least collection of one of the Incision Sites is mandatory
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.1.3 Axillary

Definition:	An incision in the axilla
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical incision locations
Data Requirement:	At least collection of one of the Incision Sites is mandatory
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.1.4 Mastectomy wound

Definition:	An incision at the site of an existing mastectomy wound or scar
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical incision locations
Data Requirement:	At least collection of one of the Incision Sites is mandatory
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.1.5 Mastopexy/reduction wound

Definition:	An incision at the site of an existing mastopexy (breast lift or reduction) wound or scar
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical incision locations
Data Requirement:	At least collection of one of the Incision Sites is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.1.6 Other

Definition:	Any other incision site
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical incision locations
Data Requirement:	At least collection of one of the Incision Sites is mandatory
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.2 Implant position/plane

6.2.1 Sub glandular

Definition:	The surgical plane in which an implant is inserted under breast tissue
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant Positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.2.2 Subfascial

Definition:	The surgical plane in which an implant is inserted under pectoralis fascia
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant Positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.2.3 Dual plane*

Definition:	The surgical plane in which an implant is inserted partially under pectoralis muscle and partly under breast tissue
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant Positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.2.4 Subpectoral

Definition:	The surgical plane in which an implant is inserted under pectoralis muscle
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant Positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.2.5 Subcutaneous/Prepectoral*

Definition:	The surgical plane in which an implant is inserted in front of pectoralis muscle
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant Positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.2.6 Subflap

Definition:	The surgical plane in which an implant is inserted under a flap
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant Positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.2.7 Other

Definition:	Another surgical plane in which an implant is inserted
Purpose:	To identify differences in the health outcomes of patients and device performance depending on the placement of the device during surgery
Data Requirement:	At least collection of one of the Implant positions/ Planes is mandatory
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.3 Nipple sparing

Definition:	Removal of the breast tissue with preservation of the breast skin envelope and the nipple and areola complex
Purpose:	To identify differences in the health outcomes of patients undergoing differing surgical methods
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.4 Nipple absent

Definition:	Absence of the nipple at the time of device insertion
Purpose:	To identify health outcomes of (reconstructive) patients who lost a nipple through previous surgery
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.5 Concurrent mastopexy/reduction

Definition:	Indicating whether the operation involves a breast reduction and/or breast lift
Purpose:	To identify differences in the health outcomes of patients undergoing adjunct breast reconstruction procedures at the time of device insertion
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.6 Concurrent flap cover

Definition:	Any type of flap used for breast reconstruction (concurrent or previous) that covers an implantable breast device or adds volume to the breast mound
Purpose:	To identify differences in the health outcomes of patients undergoing adjunct breast reconstruction procedures at the time of device insertion
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.7 Concurrent axillary surgery

Definition:	Either the patient undergoes a sentinel node biopsy or axillary clearance at the time of device insertion
Purpose:	To identify differences in the health outcomes of patients undergoing adjunct breast reconstruction procedures at the time of device insertion
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.8 Fat grafting

Definition:	Transfer of aspirated fat to the breast region
Purpose:	To identify differences in the health outcomes of patients undergoing adjunct breast reconstruction procedures at the time of device insertion
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

6.9 IF Fat grafting, Volume(mls)

Definition:	Indicating the volume of autologous fat transferred
Purpose:	To record the volume of fat transferred from another area the time of procedure
Data Requirement:	Mandatory when fat grafting is selected
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

6.10 IF Tissue Expander, Intra Operative fill volume(mls)

Definition:	Intraoperative fill volume, as determined by the surgeon at the time of the procedure
Purpose:	To record the volume contained in the device(s) inserted at the time of procedure
Data Requirement:	Mandatory when the Device Operation type is Tissue Expander
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

7.INTRAOPERATIVE TECHNIQUES

7.1 Preoperative antibiotic (before incision)

Definition:	Use of antibiotics provided IV, Orally, or IM before incision
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

7.2 Postoperative antibiotic

Definition:	Use of antibiotics provided IV, orally, or IM at any time after 3 hours post-surgery
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

7.3 Glove change before insertion

Definition:	Change of gloves immediately prior to insertion of the implant
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only procedure
Definition Source:	ICOBRA MDS Consensus study

7.4 Sleeve/Funnel

Definition:	Indicates the use of sterile, cone-shaped device to assist with "no touch" delivery of implants, thereby preventing potential contamination
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only procedure
Definition Source:	BDR Data Dictionary

7.5 Occlusive nipple shield

Definition:	The use of adhesive film dressing covering the nipple-areola complex to prevent perioperative expression of bacteria from nipple ducts contaminating the operative field
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

7.6 Drain use

Definition:	Intra-operative insertion of drains
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

7.7 Rinse of the pocket*

7.7.1 Antibiotic

Definition:	Intraoperative wash of the surgical pocket with an antibiotic solution
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

7.7.2 Antiseptic

Definition:	Intraoperative wash of the surgical pocket with antiseptic solution
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

7.7.3 Other

Definition:	Intraoperative wash of the surgical pocket with other solution
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

7.8 Dipping solution*

7.8.1 Antibiotic

Definition:	Indicates the use of an antibiotic solution for dipping the implant prior to insertion
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only procedure
Definition Source:	BDR Data Dictionary

7.8.2 Antiseptic

Definition:	Indicates the use of an antiseptic solution for dipping the implant prior to insertion
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only procedure
Definition Source:	BDR Data Dictionary

7.8.3 Other

Definition:	Indicates the use of another solution for dipping the implant prior to insertion
Purpose:	To identify specific surgical techniques utilised during surgical procedures for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Optional
Data Collection:	Collection is required except for explant only procedure
Definition Source:	BDR Data Dictionary

8.Reason for revision

8.1 Complication

Definition:	The reason for revision indicating whether the reason is due to identified medical complication or, without medical complications such as increase/decrease in size or perceived device expiry
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

8.2 Asymptomatic

Definition:	Patient has no symptoms related to implants
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

8.3 Breast cancer (not including BIA-ALCL below)

Definition:	Patient has been diagnosed with Breast Cancer
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

8.4 Patient Reported

8.4.1 Patient reported - Breast Implant Anxiety*

Definition:	Patient is concerned about the effect of implant on their health
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

8.4.2 Patient reported - Breast Implant Illness*

Definition:	Patient has symptoms that they attribute to their implants
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

8.4.3 Patient reported - Patient Preference

Definition:	Patient has chosen to have implants either removed or replaced
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

8.4.4 Patient reported - Breast Pain*

Definition:	Patient has pain in their breast which they believe may be resolved by removing implants
Purpose:	To identify the underlying reason(s) for revision surgery and separate health/surgical causes from patient choice without medical cause. This is beneficial for data analysis and reporting purposes that may guide future best clinical practice
Data Requirement:	Collection of one of the reasons for revision from 8.1 to 8.4 is mandatory if the procedure is revision
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

9. Details of explanted device

9.1 Reference Number

Definition:	Catalogue reference number of the implanted device
Purpose:	Device identification- manufacturer
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.2 UDI*

Definition:	Device unique identification number generated by the system
Purpose:	Device identification- specific device
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.3 Manufacturer

Definition:	Name of the manufacturer of the implanted device
Purpose:	Device identification- manufacturer
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.4 Date of insertion

Definition:	Date the explanted device was originally inserted
Purpose:	To assist in assessing device longevity and performance. This may identify a device safety signal that can then be reported back to manufacturers and surgeons
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.5 Shell

Definition:	The surface texture of the device being inserted
Purpose:	Identify device characteristics, potentially assists in tracking performance outcomes
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.6 Fill

Definition:	The material used to fill the breast implant: saline solution, silicone gel, or other
Purpose:	Identify device characteristics, potentially assists in tracking performance outcomes
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.7 Shape

Definition:	The shape of the device being inserted into or explanted from the breast; where the shape of the device is either Round: implant is shaped like a flattened sphere or Shaped: a contoured shape that re-creates the more teardrop outline of a mature breast
Purpose:	Identify device characteristics, potentially assists in tracking performance outcomes
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.8 Volume of Implant(mls)

Definition:	As determined (or estimated) by the surgeon at the time of the procedure
Purpose:	Device characteristics, assists with (revision) procedure planning
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.9 Is the operation removing a device inserted overseas:

Definition:	Yes or no response
Purpose:	To track performance of devices that were implanted overseas that may assist in comparative data
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

9.10 If yes, please specify country

Definition:	Name the country where the implant was inserted if known
Purpose:	This may identify a device safety signal in devices that were implanted in countries outside Australia
Data Requirement:	Optional
Data Collection:	Collection is required when the device has been explanted during procedure
Definition Source:	ICOBRA MDS Consensus study

10. Elements of Operation-Revision surgery

10.1 Capsulectomy

10.1.1 Full

Definition:	Removal of the encapsulating scar tissue surrounding the breast implant fully
Purpose:	To capture surgical removal of tissue (capsule) that has developed around a device for data analysis and reporting
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

10.1.2 Partial

Definition:	Removal of the encapsulating scar tissue surrounding the breast implant partially
Purpose:	To capture surgical removal of tissue (capsule) that has developed around a device for data analysis and reporting
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

10.2 Neo pocket formation

10.2.1 Subcutaneous*

Definition:	Formation of new pocket under skin
Purpose:	To capture how this surgical element may influence health and device performance outcomes for data analysis and reporting
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

10.2.2 Sub glandular

Definition:	Formation of new pocket under breast tissue
Purpose:	To capture how this surgical element may influence health and device performance outcomes for data analysis and reporting
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

10.2.3 Subfascial*

Definition:	Formation of new pocket under pectoralis fascia
Purpose:	To capture how this surgical element may influence health and device performance outcomes for data analysis and reporting
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

10.2.4 Submuscular

Definition:	Formation of new pocket under muscle
Purpose:	To capture how this surgical element may influence health and device performance outcomes for data analysis and reporting
Data Requirement:	Optional
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

11. Issues identified

11.1 BIA-ALCL

Definition:	A current or previous diagnosis (pathology based) of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), where BIA-ALCL is a CD30+, ALK-, T-cell derived lymphoma within the non-Hodgkin lymphoma group. This data point to include (i) Suspected and (ii) Confirmed
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

11.2 Seroma*

Definition:	An abnormal accumulation of serum around the device
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

11.3 Haematoma*

Definition:	A collection of blood adjacent to breast device
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

11.4 Mastectomy skin flap problems

Definition:	The breast skin remaining after a mastectomy is compromised
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice.
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

11.5 Deep wound infection

Definition:	Infection leading to explantation: An infection associated with a breast implant in place, which leads to its explantation. Usually involves redness, localised pain or tenderness, abscess or persistent serous liquid formation around the implant even with distinct clinical signs it might be culture-negative
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

11.6 Device malposition/rotation

Definition:	Any instance in which the implant is outside its intended position
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

11.7 Capsular contracture: Grade 1/2/3/4*

Definition:	The scar tissue that forms around implant causes the implant to feel firm. According to Baker classification: Grade I – The breast is soft and appears normal in shape. Baker Grade II – The breast is firm but appears normal in shape. Baker Grade III – The breast is firm and appears a little distorted in shape. Baker Grade IV – The breast is hard and is appears quite distorted in shape
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary and Baker classification of capsular contracture

11.8 Double capsule

Definition:	A second thin tissue layer encasing the usually textured implant subsequently leading to permanent separation from the outer capsule
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	ICOBRA MDS Consensus study

11.9 Device deflation (saline)

Definition:	The occurrence of saline implant deflation
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

11.10 Device Rupture

11.10.1 Device rupture (silicone)

Definition:	Silicone implant that has ruptured
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

11.10.2 Device rupture – Intracapsular

Definition:	Intra-capsular is a rupture involving only the silicone shell, with free silicone gel still contained by the surrounding fibrous capsule
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

11.10.3 Device rupture – Extracapsular

Definition:	Extra-capsular is a rupture involving disruption of both the implant shell and the fibrous capsule allowing silicone to be present outside capsule
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary

11.10.4 Device rupture – Distant

Definition:	Distant, is where the diffused silicone of an extra-capsular rupture has been found in any area outside the surrounding breast tissue
Purpose:	Essential information that informs specific health outcomes and device performance that may inform and guide best surgical practice
Data Requirement:	Collection of one of these issues identified from 11.1 to 11.10 is mandatory when the reason for revision is complication
Data Collection:	Collection is required
Definition Source:	BDR Data Dictionary