The Dudley Group NHS
NHS Foundation Trust

Trust Headquarters
Russells Hall Hospital
Dudley
West Midlands
DY1 2HQ

Date: 03/03/2015

FREEDOM OF INFORMATION ACT 2000 - Ref: FOI/012107

With reference to your FOI request in connection with 'Clinical trials' please see response below.

Q: I would like to know the number of people who have volunteered for clinical trials in hospitals looked after by the trust in each of the last 9 complete calendar years (i.e. 2006-2014).

A: The number of patients enrolled in clinical trials/ studies per year can be found in the Trust's Quality Report
http://dudleygroup.nhs.uk/about-us/publications/quality-report/
or in reports published for public consumption by the National Institute for Health Research/ Department of Health.

Q: Could these figures also include the number who went on to take part in clinical trials and the age and sex of all those who volunteered.

A: We do not keep this information in R&D. It is confidential to the study teams and study centres.

Q: For each year I would like to know how many of these participants suffered negative side effects as a result of participation and the number of serious injuries, illness or deaths that occurred as a result of the trials.

A: There is a set procedure for expedited reporting of all serious adverse events in clinical trials. It is not always easy to ascertain whether an event is unquestionably due to the study drug, due to another drug used in routine treatment, or due to disease progression. It is therefore more common to classify these as 'possibly' or 'probably' related to the study intervention, rather than an emphatic 'yes'. Serious adverse events in clinical trials are reported according to the categories set out in ICH GCP (Good Clinical Practice) guidelines. Criteria for reporting may also be adjusted by the study protocol: there may be certain serious adverse events which are considered commonplace in the disease and do not require expedited reporting for the study in question. This information is then collected at routine study time points. Set out below in a table is the information for the Dudley Group NHS FT for the periods you have requested, as categorised in the Research & Development Department's database. Serious adverse events fall into the following categories:

- results in death
- is life-threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect

Calendar Year	Possibly	Probably	Yes	Death
2006	4	1	5	-
2007	4	2	4	-
2008	12	1	8	1*
2009	11	-	6	1**
2010	19	-	12	-
2011	24	-	15	3***
2012	16	-	16	-
2013	12	-	14	4****
2014	11	-	-	-

*Colorectal cancer study
**Not death but long term disability in one lung cancer study
*** Colorectal cancer study and two upper gastrointestinal cancer studies
****Two malignant haematology studies; one colorectal study

Q: In the event of serious injuries, illnesses or deaths I would also like to know general details about the clinical trial from which they resulted, and general details of the serious injury or illness they suffered, or circumstances of their death

A: General types of study are indicated in the table above.

Q: For each year I would also like to know the total amount of money paid out to volunteers to take part in clinical trials and the amount paid out in compensation.

A: Participants are NOT paid for taking part in clinical trials (only applies to Phase 1 healthy volunteer studies) , although some participants MAY receive travel expenses or inconvenience payments. No compensation has ever been paid out to trial participants at DGH FT.