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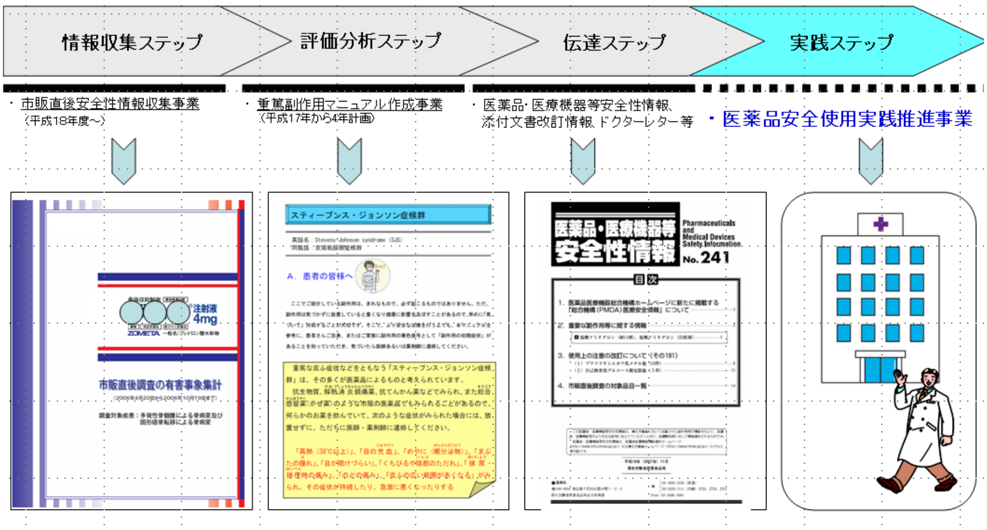
図1. 予測・予防型の医薬品安全性情報の活用ステップ



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20 19 “ ”

(500)50 100 500 150

50 100 300

20 8 9 2

19 5

(1-1 1-4)

300

139 46

MR 90

65 37 27

19 14 DSU 59 42

24 17 13

9 10

7

MR 77

36

16 48

23
9 DSU 31
48
50
21

“ ” 44 32

48
13 3 9
73 ( )

32 ( )

5
32 23

WG
WG 19
WG **1-1** 20 WG **1-2**

19

20

19

200

19 5 **2-1** 20 6
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19 **2-1** 20 **2-2**

19 **3-1** 20 **3-2**
3-3

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3-1(19) **3-2**(20

4

19 44

27

13 4

20 17

2 61

9

(a)

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Performance Status (PS)

300

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1-1 19 WG

1-2 20 WG

2-1 19

(	524	
	870	
(　)	199	
(　)	280	
(　)	725	

2-2 20

	210	
	16	
	0	
	145	
	110	
	70	

3-1 19

	PTP

3-2 20

(1-1)

2008 11 11

19

(1-2)

1 2 3

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Drug Safety Update

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	19 11 16 9 16	○
	19 11 21 9 15 16	○
	19 11 22 9 17	○
	19 11 27 9 17 10	○

20

		○
	20 12 23 13 17	○
	20 12 25 9 16	○
	20 12 20 10 16	○
	20 12 27 9 13	○
	20 12 15 9 15	○
	20 12 27 14 17	○

19 20

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12 1

(18 6 5)

12

HMG-CoA

No.226

6 2 :

6 5 : MR

6 10 :

47

12 2

7 27 : No.226

5 1

20 1

30

30

30

MR

40

50

CPK

30

MR

MR

200mg
100 150mg

50mg 100mg 1 24 60
48 70
100mg 72 1mg

Drug Safety Update DSU

4

DSU (18 10)

( )

Drug Safety Update DSU 2006.10 No.153
DSU

CCr

10 4 : DSU

10 5 :

3 2 1 50
1 150mg
150mg

5

CCr Cockcroft-Gault

CCr

CCr

CCr SCr

Cockcroft-Gault 73.6 × 0.6 = 44.16 mL/min

CCr 35 75 100mg 25 35 2
100mg 100mg

100mg

Cockcroft-Gault
CCr = (140 - age) x BW(Kg) / (72 x Cr(mg/dL))
CCr = 0.85 x CCr
CCr 0.6
0.8

DSU 2006.10 No.153

200

CCr

CCr 35 75 mL/min 100 24

CCr 75

mL/min

100

1 100mg

7

1 100

DSU /
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MR

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Drug Safety Update DSU

17 4

18 7

2

18 7

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11 3 2

18 8

80

1.25mg

25

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20 9 19

11 27

No.252 3 15

2

(20 9 19)

9 19 :

9 29 :
(MR)
8

10 8
(
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2

10 10 :

11　27　: No.252

(MR)

No.252

(　　　)

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2

2

(MR)

( )

(8)

( )

Mg

Mg

9 24 :

10 13 : MR

10 16 :

200 300
102 76
26

Mg

Mg

102 67 62 5
330mg

10 18 :
67 54 50 4 2.4mg/dL

7 0 9
0

11 27 :
No.252

12 17 :
12 24 : 9
2,000mg Mg
Mg 5.6mg/dL

1 3 21 1 5 Mg
2.5mg/dL 1 15

(MR)

102

Mg

Mg

Mg

Mg

Mg

Mg

102 76 26

Mg 5.6mg/dL

12 Mg
2.5mg/dL

Mg

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2

MR

10 20 MR
10 22 :

10 29 MR

CSV

53 327

11 29 330mg 1 80

Mg

2.7 mg/dL
1.7 2.6

18
Mg 1.9mg/dL

12 3
MR

12 5

12 15

12 20 6
6 1

MR
MR

MR No.252

Mg

20

Mg

1 0.25mg

2 1 0.5mg 1 1

0.5mg

New England Journal of Medicine NEJM 19 1 4
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FDA
19 3 29
19 19

19 6
No237

19 4 19

3 6 6 12

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4 19 :

4 20 :

4 24 :

5 1 :

5 9

5 15 :

5 22 :

3 6

6 12

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New England Journal of Medicine NEJM 19 1 4 2

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NewEngJMed

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9:30

10:00

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4 23

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8 26

41 220

3 5

AST(GOT) ALT(GPT) 1

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4 1 19 5 9

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19 8 30

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8 30

9 1

9 3

DI-News

DI-News